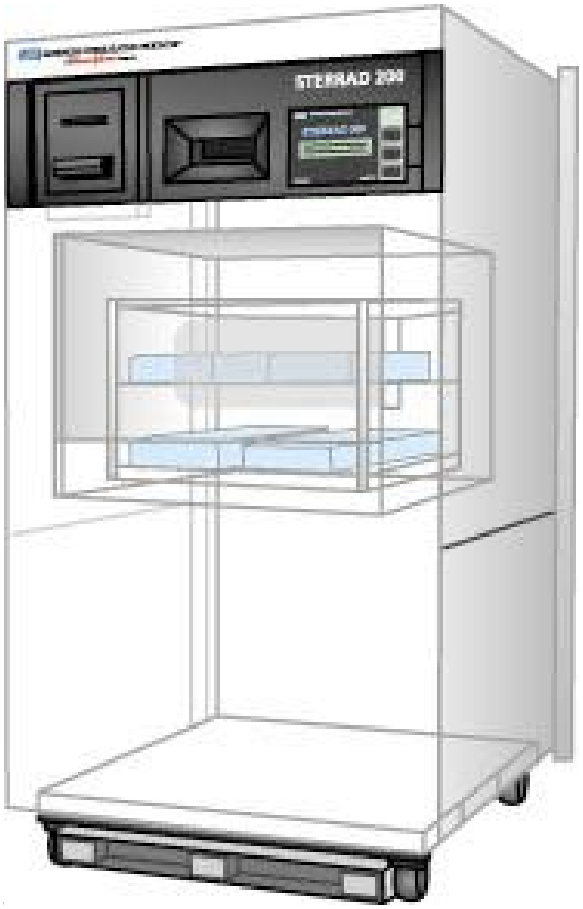
STERRAD® 200 Sterilization System

User's Guide

REF 99712



ADVANCED STERILIZATION PRODUCTS®
a Johnson & Johnson company
Division of Ethicon, Inc.

99712_01
May 2008

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For warranty information, please visit our website or
contact our Customer Care Center.
For additional copies of this guide, please visit www.e-ifu.com

Contents

About This Guide

Overview

This guide is designed to provide useful and complete information on the day-to-day operation and routine maintenance of the STERRAD® 200 Sterilizer.

The guide is divided into 6 chapters and 1 appendix. These chapters provide information on using the sterilizer, load preparation, routine maintenance, and troubleshooting the system should problems arise. The appendix contains the system specification.

The chapters and the appendix are:

- **About This Guide**-this section gives you important information on how to get the most use out of this guide.
- **Chapter 1. Introduction**-the first chapter of the guide has important details about the STERRAD 200 System including the major parts of the sterilizer and STERRAD Process information.

- **Chapter 2. For Your Safety**-this may be the most important chapter in the guide. You must read it thoroughly, understand the information, and follow all the safety procedures in this chapter. These safety procedures include safe handling of cassettes, safe transfer of sterilized materials using the two-tier shelf and carriage, and first aid information in case of possible hydrogen peroxide exposure.

- **Chapter 3. Preparing Items To Be Sterilized-**this chapter provides details on preparing items to be sterilized, packaging the load, using the two-tier shelf and carriage to transfer the load to the sterilizer and a brief description of the items that can be sterilized in the STERRAD 200 System.

- **Chapter 4. Day-to-Day Operation**-this chapter gives you detailed information on how to use the sterilizer. It shows you the typical displays that you will see as you use the sterilizer and the different screens available to the operator and administrator level passwords. It details how to use the touch screens and how to run cycles.

- **Chapter 5. Routine Maintenance-**the routine maintenance of the STERRAD 200 Sterilizer is very minimal. This chapter shows you how to change the printer paper and ribbon and what steps to follow to keep the sterilizer clean.

- **Chapter 6. Troubleshooting-**the STERRAD 200 Sterilizer displays a number of messages to tell you what the system status is at any given moment. Many of these messages do not require any action from you. Others require that you call your ASP service representative.

- **Appendix A. Specifications**-this appendix provides tables detailing the technical data relevant to the STERRAD 200 Sterilizer. Size, electrical requirements, equipment rating and an explanation of the warning symbols used on the sterilizer are some of the information found in this appendix.

Chapter 1.

Introduction

Overview

The STERRAD® 200 Sterilization System is a general purpose, low temperature sterilizer using the STERRAD Process to inactivate microorganisms on a broad range of medical devices and surgical instruments. This sterilizer offers an effective, safe, fast, economical, easy to use, reliable, and flexible sterilization method.

The length of all cycle phases and the setpoints for all critical process parameters are controlled by a microprocessor and software. The system reliably sterilizes various material and load configurations, without leaving toxic residue.

The system consistently provides 10^{-6} sterility assurance level, as defined by international standards, for clinical use on all allowed substrates within the limits of the claims for materials and geometries.

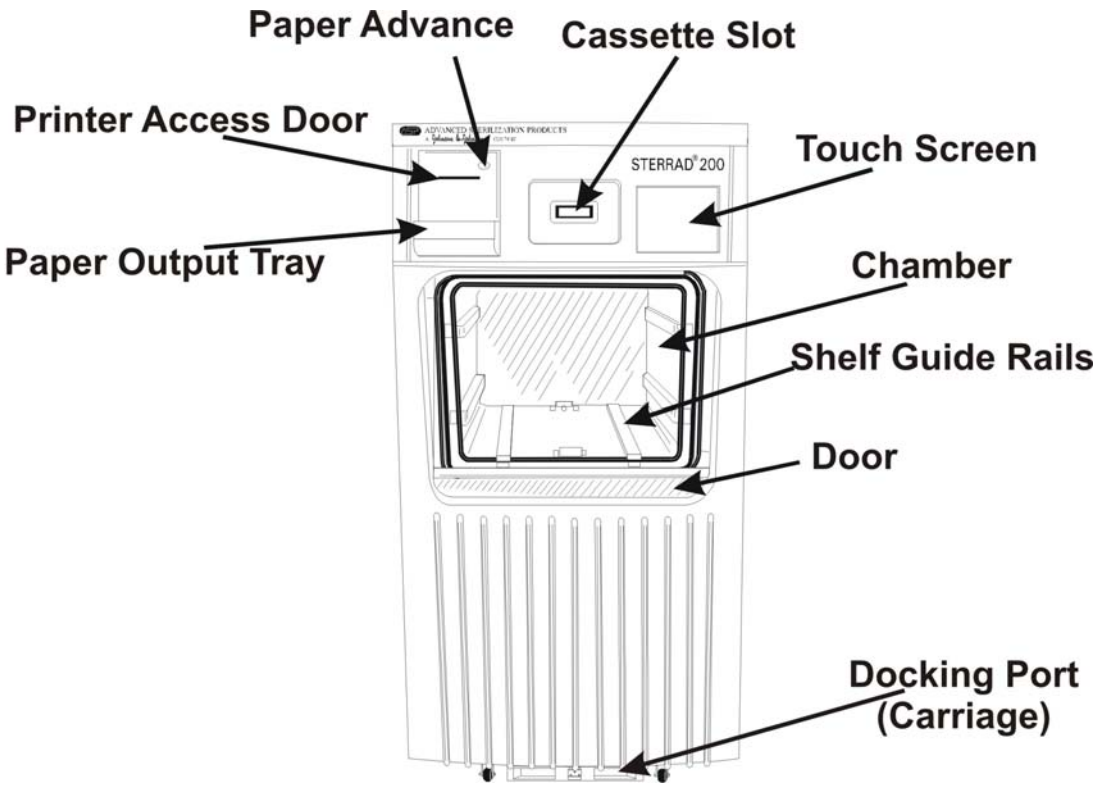


Figure 1. STERRAD® 200 Sterilizer input side on a two door unit, or front side on a one door unit.

System Details

Here are details of the important parts of the STERRAD 200 Sterilizer.

- The items to be sterilized are placed on the two-tier shelf. The two-tier shelf (see the following diagram) has 1 adjustable, removable shelf and a fixed bottom shelf. The packed two-tier shelf is easily moved, using the carriage, into or out of the sterilizer.

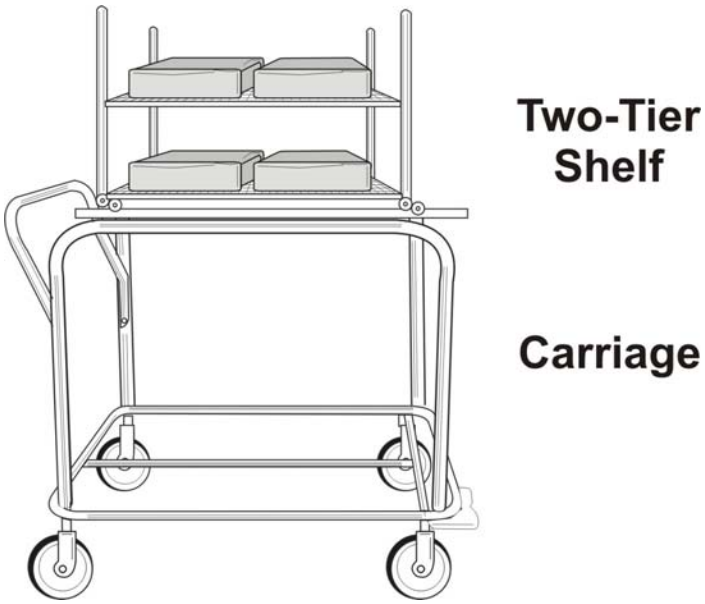


Figure 2. STERRAD® 200 Two-Tier Shelf and Carriage

- The carriage is used to move the two-tier shelf into position. This carriage is a wheeled unit that locks onto the front of the machine so that you can easily transfer a large load into or out of the sterilizer.

- Your system may have one or two doors. If you have a two-door unit, a door is located on each side of the unit. One side, the input side, is used for moving wrapped items to be sterilized into the sterilizer. The other side, the output side, is used to remove the sterile items from the sterilizer. These sterile items are then usually moved into a sterile storage area. On the one door unit, the door is used for both input and output.

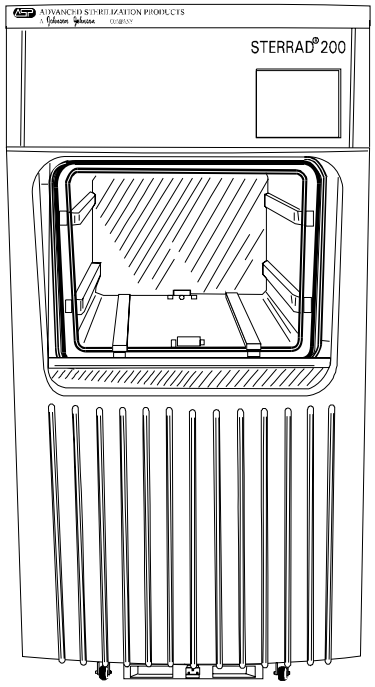


Figure 3. STERRAD® 200 Sterilizer–output side on a two door unit. Note the absence of a cassette slot.

- A touch screen computer display, mounted on the upper right front of the sterilizer, enables you to operate the sterilizer. There is a touch screen on each side of the double door unit.

- A printer, located on the upper left front panel of the unit, delivers printed messages, process parameters, and other information for your permanent records. There is usually only one printer on the unit regardless of the number of doors, however other printer options are available. Contact the ASP Customer Care Center for more details.

- There is an optional barcode scanner available for the sterilizer. The barcode scanner is used to conveniently enter bar-coded data from product tags, labels or other items.

- The usable chamber capacity is approximately 150 liters.

Chapter 2.

For Your Safety

Overview

Your safety is of primary concern to ASP. This chapter provides information on safely using the sterilizer. **You must read, understand and use the information in this chapter before operating the unit.** Also, always pay attention to the warnings, cautions and notes throughout this guide. This information is for your safety and to ensure that you receive the most benefit from the safe operation of your STERRAD® 200 Sterilization System.

Personal Safety and First Aid

- **WARNING! HYDROGEN PEROXIDE IS CORROSIVE**
  Concentrated hydrogen peroxide is corrosive to skin, eyes, nose, throat, lungs, and the gastrointestinal tract. Always wear chemical resistant latex, PVC (vinyl), or nitrile gloves when removing items from the sterilizer following a cancelled cycle or if any moisture is noted on items in the load following a completed cycle.

- **WARNING! HYDROGEN PEROXIDE IS AN OXIDIZER**
  Hydrogen peroxide is a strong oxidizing agent and poses a hazard for fire, explosion, or container rupture. Avoid allowing hydrogen peroxide to contact organic materials, including paper, cotton, wood, or lubricants. Do not use or store near heat or open flame. Shoes, clothing, or other combustible material that have come into contact with hydrogen peroxide must be immediately and thoroughly rinsed with water to avoid a potential fire hazard. In case of fire, use only water to extinguish.

- **WARNING! CONCENTRATED HYDROGEN PEROXIDE IS TOXIC**
  Ingestion of hydrogen peroxide may be life threatening. If swallowed, call a "poison control" center or physician immediately for treatment advice. Have the person drink plenty of water if the person is able to swallow. Do not give anything by mouth to an unconscious person. Do not induce vomiting unless instructed to do so by the poison control center or physician.

- **WARNING! RISK OF EYE INJURY**
  Direct hydrogen peroxide contact with eyes can cause irreversible tissue damage. If contact with eyes occurs, hold the eyes open and flush with large amounts of water for at least 15-20 minutes. Remove contact lenses, if present, and then continue rinsing the eyes. Consult a physician immediately after flushing the eyes.

- **WARNING! RISK OF RESPIRATORY IRRITATION**
  Inhalation of hydrogen peroxide mist can cause severe irritation of lungs, throat, and nose. If inhalation occurs, move the person to fresh air. If the person is not breathing, call for emergency medical attention, or an ambulance, then give artificial respiration, preferably mouth-to-mouth, if possible. Consult a physician immediately.

- **WARNING! RISK OF SKIN INJURY**
  Direct hydrogen peroxide contact with the skin can cause severe irritation. Wear chemical resistant latex, PVC (vinyl) or nitrile gloves when handling used cassettes or ejected cassettes, items from a cancelled cycle, or items that have moisture present after a completed cycle. Immediately take off contaminated clothing and rinse thoroughly with water to avoid potential fire hazard and wash before re-use.

- **WARNING! HEATED STERILIZATION SURFACES.**
  At the end of a cycle, the interior of the sterilizer may be hot. Do not touch the inside of the chamber or door with your bare or gloved hands. The vaporizer may be hot. Do not touch it with your bare or gloved hands. Allow the sterilizer to cool before touching interior surfaces.

♦ **WARNING! RISK OF BREATHING DIFFICULTIES**
On rare occasions, the outlet filter on the vacuum pump can prematurely fail. If this occurs, you may see mist or what some users have described as “haze” or “smoke” in the room where the sterilizer is operating. The chemical composition of the mist is primarily airborne mineral oil with trace amounts of other compounds. Oil mist exposure may, theoretically, pose an increased risk to people with certain respiratory conditions, such as asthma, and they should take special precautions not to be exposed to the mist. If you observe these conditions, personnel should leave the room as a precaution and discontinue use of the STERRAD System until the system is repaired. Personnel should avoid working in the room until the mist has cleared.

Please note that all STERRAD Sterilizers should be used and installed in a well-ventilated environment (a minimum of 10 air exchanges per hour).

Device Safety

- **DO NOT ATTEMPT TO STERILIZE ITEMS OR MATERIALS THAT DO NOT COMPLY WITH THE GUIDELINES SPECIFIED IN THIS GUIDE.** In addition, you should read the medical device manufacturer's instructions, or call the ASP Customer Care Center to determine whether an item can be sterilized by this unit. Information may also be obtained from the device manufacturer.

- All items must be cleaned and thoroughly dried before loading into the sterilizer. Loads containing moisture may cause cycle cancellation.

- The chapter on preparing items to be sterilized contains information about the materials and devices that can be processed by the STERRAD 200 Sterilizer.

- Metal objects must not come into contact with the chamber walls, the doors or the electrode. Contact with the walls, doors, or electrode could damage the sterilizer or instruments.

- Do not change the power source without checking the electrical phase rotation. Prior to relocating the STERRAD 200 Sterilizer to a new power source, electrical phase rotation should be checked by a qualified technician. Failure to verify and match phase rotation may cause damage to the sterilizer and void the warranty.

- If you plan to disconnect and store the sterilizer for any length of time, please contact your ASP service representative at 1-888-STERRAD (1-888-783-7723) for instructions.

- An ASP-approved biological indicator (BI) should be used to monitor the sterilization cycle. Should a cancellation occur when a biological indicator is in the chamber, discard the biological indicator and then use a new biological indicator when re-starting the cycle. Call the ASP Customer Care Center for information on approved biological indicators.

Cassette Handling

- **STERRAD 200 CASSETTES CONTAIN CONCENTRATED HYDROGEN PEROXIDE, A STRONG OXIDIZER. CONCENTRATED HYDROGEN PEROXIDE IS CORROSIVE TO SKIN, EYES, NOSE, THROAT, LUNGS, AND GASTROINTESTINAL TRACT**. Direct contact with the skin can cause severe irritation. If skin contact occurs, immediately flush with large amounts of water. If symptoms are severe or persist, consult a physician immediately. Direct contact with eyes can cause irreversible tissue damage. If eye contact occurs, immediately flush with large amounts of water and immediately consult a physician. Inhalation of mist can cause severe irritation of lungs, throat, and nose. If inhalation occurs, move to fresh air and consult a physician immediately. Ingestion can produce corrosion that may be life threatening. If swallowed, drink plenty of water immediately to dilute. Do not induce vomiting. Consult a physician.

- Do not remove the plastic wrapper from the cassette package if the indicator strip is red. Red indicates that the cassette might have been damaged. Call the ASP Customer Care Center for more information.

- Do not remove used cassettes from the protective cardboard sleeve. Dispose of the cassette inside the protective sleeve according to your facility's procedures.

- If it is necessary to handle a used cassette that is not in the cardboard sleeve, wear chemical resistant latex, PVC (vinyl) or nitrile gloves. Do not touch your gloved hands to your face or eyes.

Safe Maintenance

- **WARNING! HYDROGEN PEROXIDE MAY BE PRESENT**
  If white residue is visible on the load; this may be residue from the hydrogen peroxide stabilizer. Wear chemical resistant latex, PVC (vinyl), or nitrile gloves when removing a load with visible white residue. White residue can be minimized by making sure regular Planned Maintenance (PM) procedures are performed on your sterilizer. The sterilizer will inform you when Planned Maintenance is due. Please schedule your PM service in a timely manner.

- Repairs and adjustments should only be attempted by experienced technicians who are fully trained to maintain and repair the STERRAD 200 Sterilizer.

- Use of unauthorized parts for maintenance or repair could cause personal injury, result in costly damage or unit malfunction, and void the warranty.

- Do not clean the chamber door area with abrasives. The sterilization chamber uses an O-ring vacuum seal to maintain a vacuum in the chamber. Never use rough cleaning tools, such as a wire brush or steel wool, on the door housing or chamber assembly. This could damage the seal.

Additional Information

- The information contained in this chapter is repeated where appropriate throughout this guide for your safety and use. This information is subsequently labeled: WARNINGS, Cautions or Notes as appropriate.

- **WARNINGS** are shown in the text in all bold upper case letters. They indicate events or conditions that can result in serious injury or death.

- **C**autions are shown in the text in bold letters. They indicate events or conditions that can result in damage to equipment.

- Notes are shown in the text with a check mark ✔. They highlight specific information about the proper use and maintenance of the STERRAD 200 Sterilizer.

Chapter 3.

Preparing Items To Be Sterilized

Overview

The STERRAD® 200 Sterilizer can process many of the items you commonly sterilize as well as instruments that are sensitive to heat and moisture. However, there are a few important exceptions. Please review the "How to Determine What Can be Sterilized in the STERRAD 200 System" foldout page contained in this chapter. It contains details on recommended materials and lumen sizes.

Indications for Use

The STERRAD 200 Sterilizer is designed for sterilization of both metal and nonmetal medical devices at low temperatures. Because the cycle operates within a dry environment and at low temperatures, it is especially suitable for instruments sensitive to heat and moisture. The sections that follow contain more information on the types of items and materials that can be sterilized in the STERRAD 200 Sterilizer.

- The STERRAD 200 Sterilizer can sterilize instruments having diffusion-restricted spaces, such as the hinged portion of forceps and scissors.
- Teflon® or polyethylene lumened instruments with inside diameters of 6 mm or larger and lengths of 310 mm or shorter can be processed in the STERRAD 200 Sterilizer.
- Medical devices with only a single stainless steel lumen with:

- an inside diameter of 1 mm or larger and a length of 125 mm or shorter,*
- an inside diameter of 2 mm or larger and a length of 250 mm or shorter,*
- an inside diameter of 3 mm or larger and a length of 400 mm or shorter.

can be processed in the STERRAD 200 Sterilizer.

*Validation testing for this lumen size was conducted using a maximum of 12 lumens per load. Your loads should not exceed the maximum number of lumens validated by this testing.

✔ ***Note:*** *The validation studies for this sterilizer were performed using the STERRAD cycle consisting of a 6-minute, 45-second injection phase followed by a 2-minute diffusion phase, and a 2-minute plasma phase. The validation studies were performed using a validation load consisting of four instrument trays, each weighing 9.12 lbs. (the total weight of the load was 36.48 lbs.).*

✔ ***Note****: Determination of true length is based upon actual instruments identified as intended for reprocessing and meet all other criteria for processing in the STERRAD 200 Sterilizer.*

WARNING! DO NOT ATTEMPT TO STERILIZE ITEMS OR MATERIALS THAT DO NOT COMPLY WITH THE GUIDELINES SPECIFIED IN THIS GUIDE. IN ADDITION, YOU SHOULD READ THE MEDICAL DEVICE MANUFACTURER'S INSTRUCTIONS, OR CALL THE ASP CUSTOMER CARE CENTER TO DETERMINE WHETHER AN ITEM CAN BE STERILIZED BY THIS UNIT.

How to Determine What Can be Sterilized in the STERRAD® 200 System

The following page is a chart that unfolds to show you detailed lists of recommended items, materials, and some typical devices that can be sterilized in the STERRAD 200 Sterilizer. You should refer to it whenever you need materials information. Be sure to check with the medical device manufacturer's instruction before loading any item into the STERRAD 200 Sterilizer.

- **Important!** Stainless steel, polyethylene, and Teflon® are the only types of lumens that can be sterilized in the STERRAD 200 Sterilizer.

✔ ***Note:*** *There are a wide variety of materials and devices that can be sterilized in the STERRAD 200 Sterilizer. As more manufacturers complete testing of their products with the STERRAD 200 Sterilizer, the range of recommended and/or compatible items grows. ASP maintains updated information and we are happy to share it with you. Please contact the ASP Customer Care Center for an up-to-date list of recommended materials, devices and/or device manufacturer information. Call 1-888-STERRAD (1-888-783-7723).*

How To Determine What Can Be Sterilized In The STERRAD® 200 Sterilizer

1 Is The Reprocessable Medical Device Made Of The Following Materials?**

** This list of materials does not apply to trays and containers or other packaging materials. Please refer to the STERRAD® 200 User's Guide for information on appropriate packaging materials for use in the STERRAD System.

- Aluminum
- Brass
- Delrin® acetal resin (polyacetal)†
- Ethylvinyl acetate (EVA)
- Glass
- KRATON™ Polymers
- Neoprene†
- Non-mated Nylon® (polyamide)†
- Polycarbonate
- Polyethylene
- Polyetherimide (ULTEM® Polymers)
- Polymethyl methacrylate (PMMA)††
- Polyphenylene sulfone (Radel®)†
- Polypropylene
- Polystyrene
- Polyurethane
- Polyvinyl chloride (PVC)
- Silicone elastomers
- Stainless steel
- Teflon® (polytetrafluoroethylene)
- Titanium

† May have limited life after repeated sterilization.
Delrin®, Nylon®, and Teflon® are registered trademarks of the DuPont Corporation.
KRATON™ Polymers is a trademark of KRATON Polymers U.S. L.L.C.

ULTEM® Polymers is a registered trademark of the GE Company.
†† Contact ASP or the device manufacturer to determine the compatibility of any device manufactured from PMMA.

No/Don't Know → Please call the device manufacturer for information on how to properly sterilize this device.

Yes

2 Does The Reprocessable Medical Device Have A Lumen?

No → Proceed with Processing.

Yes

3 Is The Lumen Made Of Stainless Steel, Or Teflon®?

No/Don't Know → Please call the device manufacturer for information on how to properly sterilize this device.

Yes

4 Proceed With Processing If The Lumen Conforms To The Dimensions Listed Below

Stainless Steel Lumen

Inside Diameter	Length
1 mm or larger	125 mm or shorter*
2 mm or larger	250 mm or shorter*
3 mm or larger	400 mm or shorter

Teflon®/Polyethylene Lumens

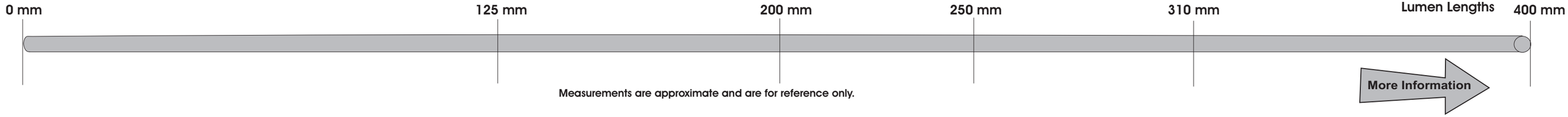
Inside Diameter	Length
6 mm or larger	310 mm or shorter

* Validation testing for this lumen size was conducted using a maximum of 12 lumens per load. Your loads should not exceed the maximum number of lumens validated by this testing.

If the lumens do not conform to these dimensions, please call the device manufacturer for information on how to properly sterilize these devices. Lumens not conforming to these dimensions should not be processed in the STERRAD 200 Sterilizer.

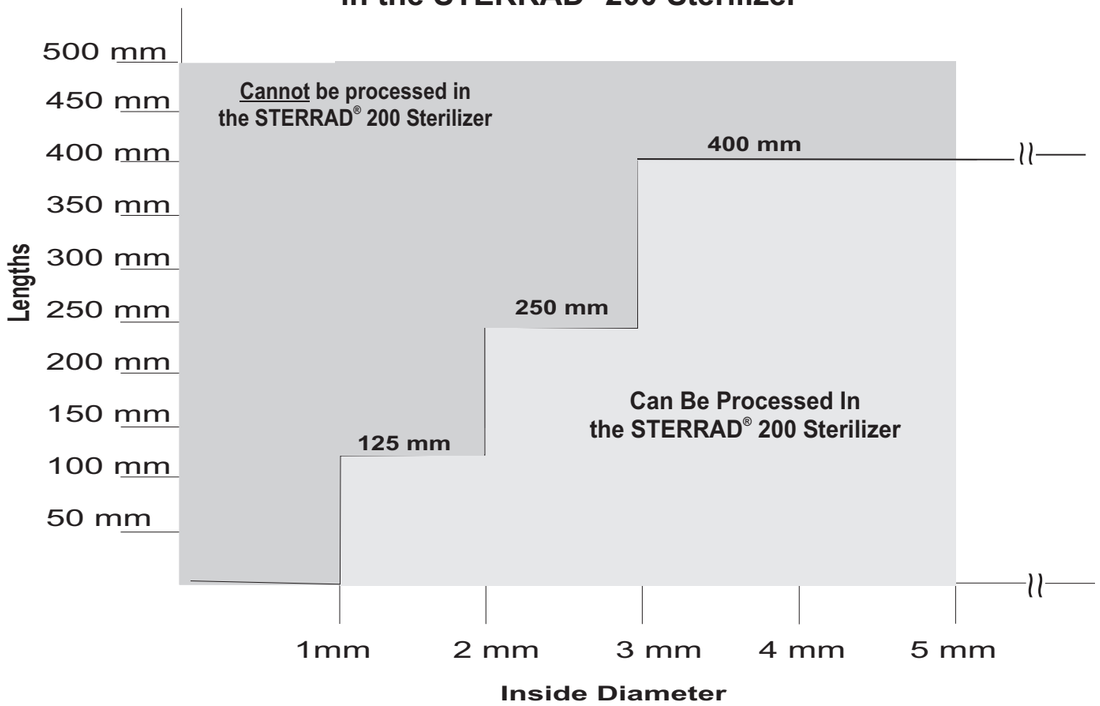
Inside Lumen Diameters

- 1 mm (0.039 inches)
- 2 mm (0.078 inches)
- 3 mm (0.118 inches)
- 4 mm (0.157 inches)
- 5 mm (0.196 inches)
- 6 mm (0.236 inches)



Measurements are approximate and are for reference only.

Processing Stainless Steel Lumens in the STERRAD® 200 Sterilizer



Typical Devices Sterilized in the STERRAD® 200 Sterilizer*

- Stereotactic equipment
- Defibrillator paddles
- Electrocautery instruments
- Esophageal dilators
- Cranial pressure transducer cables
- Metal instruments
- Patient lead cables
- Endoscopic instruments
- Rigid endoscopes
- Laryngoscope blades
- Trocar sheaths
- Cryoprobes
- Surgical power equipment and batteries
- Fiberoptic light cables
- Laser hand-pieces, fibers, and accessories
- Ophthalmic lenses (diagnostic, magnifying)
- Pigmentation hand-pieces
- Dopplers
- Shaver hand-pieces
- Radiation therapy equipment
- Ultrasound probes
- Video cameras and couplers
- Resectoscope/working elements and sheaths

If you have questions about whether your particular device can be sterilized in the STERRAD Sterilizer, please call the device manufacturer or call ASP at 1-888-STERRAD. Visit our website at www.sterrad.com.

* Any devices processed in the STERRAD 200 Sterilizer must be within the claim limits of the sterilizer.

Items Not Recommended

- Items made with copper or copper alloys (such as Monel), should not be used. Please contact the ASP Customer Care Center at 1-888-STERRAD for more information.
- Instrument mats other than STERRAD Instrument Mats.
- Instrument trays other than STERRAD Instrument Trays or APTIMAX® Instrument Trays.
- Any item that is not completely dry.
- Items or materials that absorb liquids.
- Items made of materials that contain cellulose, such as cotton, paper or cardboard, linens, huck towels, gauze sponges, or any item containing wood pulp.
- Paper instrument count sheets or lot stickers.
- Liquids and powders.
- Items with mated, Nylon® surfaces.
- Single use items for which the manufacturer does not recommend resterilization.
- Implants for which the manufacturer has not specifically recommended sterilization in the STERRAD 200 Sterilizer.
- Instruments and devices that cannot withstand a vacuum and are labeled for gravity steam sterilization methods only.
- Items whose design permits the surfaces to collapse onto each other unless some method is used to keep the surfaces separated.
- Devices with internal parts, such as sealed bearings, that cannot be immersed may present difficulties in cleaning and should not be processed in the STERRAD 200 Sterilizer.

Cleaning, Rinsing, and Drying

Cleaning and sterilization are two separate processes. Proper cleaning of instruments and devices is a critical and necessary step prior to sterilization.

- All items including trays must be thoroughly cleaned, rinsed, and dried before loading into the sterilizer.

- Carefully inspect all instruments and devices for cleanliness and dryness prior to packaging. If visible soil is present, the item must be re-cleaned and dried prior to sterilization. If moisture is present, dry the item thoroughly prior to sterilization.

- Carefully inspect all instruments and devices for flaws or damage prior to packaging. Devices and instruments with flaws or damage should be replaced or repaired before using.

  ✔ ***Note**: Periodic careful inspection of the items after repeated exposure to disinfectant/cleaner/sterilant is necessary, due to the potential damaging effects of the chemical agents on the items.*

Cleaning is necessary to remove organic and inorganic soil and debris from equipment. This process also removes many microorganisms from the surface of the items. Sterilization then inactivates all remaining spores and live microorganisms.

- **Clean** your devices according to the medical device manufacturers' instructions. You must remove all blood, tissue, and soil from items using appropriate detergents, cleansers and/or methods.

- **Rinse** items thoroughly to remove detergent or cleanser residue. Use treated water that is of a quality that ensures hard water stains do not occur. Failure to remove all organic materials or detergents may result in the formation of light-colored residue on the devices. If residue is visible, you should clean, rinse, dry, and resterilize the device prior to use.

- **Dry all items thoroughly**. An acceptable method for drying is to blow compressed gas through the lumen until no moisture exits the distal end of the device. Please ensure that any method used to dry the devices is in accordance with the manufacturers' instructions for use or contact the device manufacturer to obtain appropriate and safe procedures. It is necessary to remove moisture from all parts of the items. **Only dry items should be loaded into the sterilization chamber to prevent cycle cancellation**.

WARNING! POSSIBLE RESIDUAL HYDROGEN PEROXIDE CONTACT! FAILURE TO ENSURE THAT INSTRUMENTS ARE COMPLETELY DRY BEFORE THEY ARE PROCESSED IN THE STERRAD® STERILIZER MAY RESULT IN RESIDUAL HYDROGEN PEROXIDE BEING PRESENT ON THE OUTER SURFACE OF THE LOAD. THIS MAY CAUSE CONTACT BURNS WHEN THE SURFACE OF THE LOAD IS HANDLED.

- Some complex reusable medical devices may require disassembly for proper cleaning and sterilization. It is very important that you follow the device manufacturers' recommendations concerning cleaning and sterilization. In the absence of STERRAD® System-specific instructions, please contact the relevant medical device manufacturer.

WARNING! POSSIBLE NON-STERILE DEVICE! LOADS CONTAINING MOISTURE MAY RESULT IN EITHER A NON-STERILE DEVICE OR CYCLE CANCELLATION. WEAR CHEMICAL RESISTANT LATEX, PVC (VINYL), OR NITRILE GLOVES WHEN HANDLING ITEMS FROM ANY LOAD CONTAINING MOISTURE.

Guidelines for Wrapping, Packaging, and Loading

Proper preparation of trays, pouches, and instruments can minimize or prevent cycle cancellation and positive BI results due to load-related problems.

- Only STERRAD and APTIMAX® Instrument Trays and STERRAD Accessories are recommended for use in the STERRAD 200 Sterilizer. STERRAD and APTIMAX® Instrument Trays are specially designed to allow diffusion of hydrogen peroxide and the plasma around all the items in the load. The trays should only be padded with STERRAD Instrument Tray Mats or polypropylene sterilization wrap. Do NOT use linen, cellulosic, or any materials shown in the "Items Not Recommended" list. Follow the instructions for use included with the STERRAD Instrument Tray Mats to determine the number of mats that can be used at one time in the chamber.

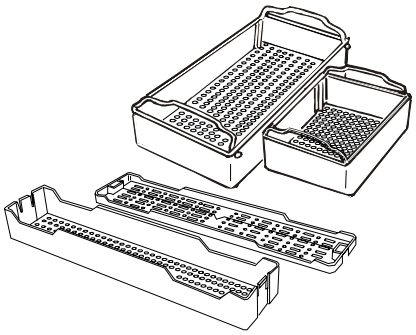


Figure 4. Use only STERRAD® Instrument Trays and APTIMAX® Instrument Trays

- Improper loading of the sterilizer may result in cycle cancellations and/or positive biological indicator results.
- Configure loads with a combination of metal and nonmetal items, and wrapped trays and pouches to maximize the efficiency of the cycle.
- Do not use foam pads in instrument trays. They may absorb the hydrogen peroxide.
- Do not use any wraps or packaging that are not approved by ASP and listed in the previous section on "items not recommended."

- Use only STERRAD 200 Sterilizer compatible polypropylene sterilization wrap and Tyvek® pouches. Do not use paper pouches or sterilization wraps containing cellulose or cotton.
- Place STERRAD Chemical Indicator Strips inside trays and Tyvek® pouches.
- Secure all wraps with STERRAD SealSure® Chemical Indicator Tape.
- Arrange items to ensure that the hydrogen peroxide and plasma can contact all surfaces.
- Place peel pouches loosely on edge, if possible. Arrange them so that the transparent side of a pouch faces the opaque side of the next pouch. Do not stack pouches on top of each other.
- Do not allow any item to touch the walls of the sterilization chamber, doors, or electrode.

✔ ***Note:*** *Do not stack instruments inside the trays. Do not stack trays. Do not stack trays within trays. Do not wrap instruments within a wrapped tray.*

✔ ***Note:*** *If you are using rigid containers cleared by the FDA for use in the STERRAD System, follow the same procedures that are recommended for use with the STERRAD or APTIMAX® Instrument Trays. Do not stack instruments inside the containers. Do not stack containers. Do not stack containers within containers. Do not wrap instruments within the containers.*

Caution: Metal objects must not come into contact with the walls of the sterilization chamber, door, or electrode. Contact with the walls, door, or electrode can interrupt the plasma phase of the process, cause a cycle cancellation, and/or damage the item or the sterilizer.

- Provide at least 25 mm (1 inch) of space between the ceiling of the electrode and the top of the load.
- Place STERRAD CycleSure® Biological Indicator (BI) or an ASP-approved biological indicator in the chamber. Frequency of biological testing should be at least once per day or in accordance with your facility's policy. Review the instructions included with the biological indicator to ensure proper use.
- Proceed to "Chapter 4. Day-to-Day Operation" for information on starting a cycle.

Chapter 4.

Day-to-Day Operation

Safe Operation

Before operating the STERRAD® 200 Sterilizer, you must thoroughly *read, understand and follow* the information in "Chapter 2. For Your Safety" as well as "Chapter 3. Preparing Items for Sterilization."

Sterilizer Operation

The STERRAD 200 Sterilizer automatically monitors and controls the sterilization process. The STERRAD 200 Sterilizer reports its status in three ways:

- **Touch Screen (flat panel, high color VGA Display)**–The display indicates the status of the unit at all times the unit is powered on. It also indicates the time remaining to cycle completion. There is a display on each side of the sterilizer in the two-door configuration. The display on the output side may not be active at all times and may not allow you to perform as many functions as on the input side.

Figure 5. Main Display. Touch anywhere to begin.

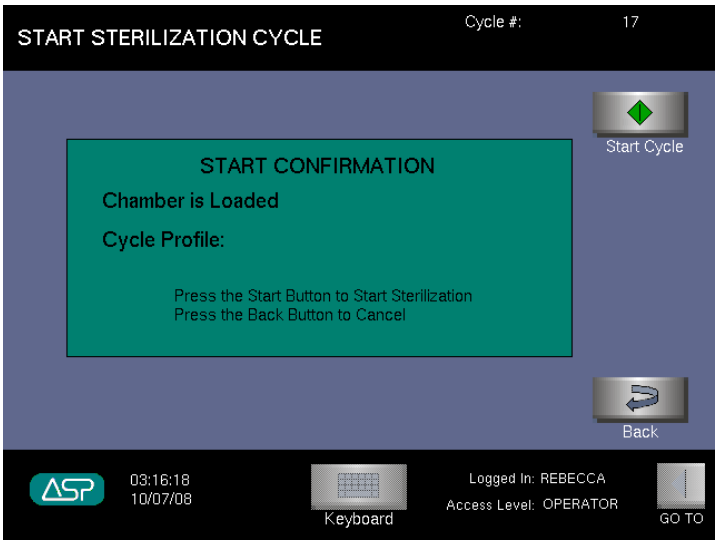


Figure 6. Touch Start Cycle to begin sterilization. This display is seen after log in and the Load Item Data display. Your display may be slightly different. Touch Back to return to the Load Item Data display.

- **Paper printout**–A printed record is produced after each cycle completion or cancellation. This is a record of the cycle parameters and may be kept for your records. The print should be completely black. Red print indicates a problem with the cycle. The printer is located behind the printer door on the upper left panel on the input side.

- **Beeps**–Beeps alert you when a cycle is complete, or a cancellation has occurred. A long beep indicates a complete cycle.

Display Sequence

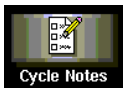
Following is an abbreviated version of the displays that appear, and the steps required, during the start-up, processing, and the completion of a cycle.

- Log in on the input side (if login is enabled).
- Load items into the sterilizer.
- Enter load item data (if desired and if login is enabled).
- Start the cycle.
- Cycle completes. System logs the user out from the input side.
- Log in required on the output side (if enabled).
- Review the cycle summary results.
- Log out.

Using the Displays

The following table presents typical buttons that you use to perform tasks related to sterilizing your instruments or to actually starting the sterilization cycle. These buttons do not appear on all displays. On two door units, the current display is shown on both sides. However, only one side at a time has an active touch screen. The active side is the input side when items are being loaded, load item data is being entered and the cycle is in progress. The output side is the active side when a cycle has completed successfully and the load can be removed.

Button	Function
	Touch to begin the sterilization cycle.
	Touch to cancel a cycle or any other operation.
	Touch to open the sterilizer door. This button is only available when the cycle is not running. The door it controls is the door on the active side. You cannot open both doors at once. The Close Door button has the arrow pointing upwards.
	Touch to return to the previous display.
	Touch to confirm an action you have taken.
	Touch to open the Function Button Bar. This button bar has different button choices depending on whether the system is running a cycle, is being serviced, or is idle.
	Touch to log in to the system prior to running a cycle. Also, allows you to log out from the system.
	In the password administration display, touch this button to add a new user. You may not have access depending on your password level.

Button	Function
	In the password administration display, touch this button to modify existing information for the selected user; i.e., password, etc. You may not have access depending on your password level.
	Touch to open the system configuration display. You may not have access depending on your password level.
	Allows input of settings for connection to a computer network. You may not have access depending on your password level. You must contact your ASP service representative prior to performing this set-up.
	Touch to change the date and/or time. This button appears on the Function Button Bar on systems configured to operate without ID and password login.
	Touch to display the utilities menu. This menu includes, Cycle History, File Management, System Set-up and Diagnostics. You may not have access to all menus choices depending on your password level.
	Touch to open the Cycle Notes display. Enter text relevant to the load that is being processed. These notes are only applicable to the current cycle and can be printed.
	Touch to print the information displayed.
	Touch to collapse the Function Button Bar. (**GO TO...** is displayed when the Function Button Bar is closed.)
	Touch to expand or collapse the virtual keyboard. This button may not be available on all displays.

Function Button Bar Displays

The Login button is explained in the section on passwords. Touching **Close** collapses the Function Button Bar. The other buttons are explained in the preceding table. An alternate Function Button Bar is only seen when the system has been configured at installation to operate without an ID or a password. With this configuration, the date and time function is available to the operator. If the system is configured to require an ID and password, the date and time function is part of the system setup menu and is available to Administrator level passwords (or higher) by pressing the **Utilities** button.

- Pressing **Utilities** displays a login screen.
- The other buttons function in the same manner as previously explained.

Preparing the Load

Proper preparation of trays, pouches, and instruments can minimize or prevent cycle cancellation due to load-related problems. The two-tier shelf may be used in two ways: it can be used with the carriage to transfer the load into, and remove it from, the sterilizer. It may also remain in the sterilizer and the items to be sterilized can be placed on the two-tier shelf without the use of the carriage. Regardless of whether the carriage is used, the two-tier shelf *must* be used. Items cannot be placed in the sterilization chamber without using the two-tier shelf. More information on load preparation is found in "Chapter 3. Preparing Items for Sterilization."

- Arrange the items in a tray to ensure that the hydrogen peroxide and plasma can surround them. Do not stack basins within the trays.
- Place trays flat on the two-tier shelf. Do not stack trays.
- Place peel pouches on edge, if possible. Arrange them so that the transparent side of a pouch faces the opaque side of the next pouch. Do not stack pouches on top of each other.
- Do not allow any item to touch the walls of the sterilization chamber or the electrode.
- The load must not project above the top or beyond the edges of the two-tier.
- When needed, place an ASP-approved biological indicator in the sterilization chamber at the back of the bottom shelf.

- Provide at least 25 mm (1 inch) of space between the electrode and the top of the load.

✔ ***Note:*** *Do not stack instrument inside the trays. Do not stack trays. Do not stack trays within trays. Do not wrap instruments within the trays.*

✔ ***Note:*** *If you are using rigid containers cleared by the FDA for use in the STERRAD System, follow the same procedures that are recommended for use with the STERRAD or APTIMAX® Instrument Trays. Do not stack instruments inside the containers. Do not stack containers. Do not stack containers within containers. Do not wrap instruments within the containers.*

CAUTION: Metal objects must not come into contact with the chamber walls, the doors or the electrode. Contact with the walls, doors, or electrode could damage the sterilizer or instruments.

Biological Indicators

Confirming that sterilizing conditions were achieved during a cycle is an important part of the sterilization process. Biological indicators (BIs) are one way to ensure that your sterilizer is operating correctly. Frequency of biological testing should be at least once per day or in accordance with your facility's policy.

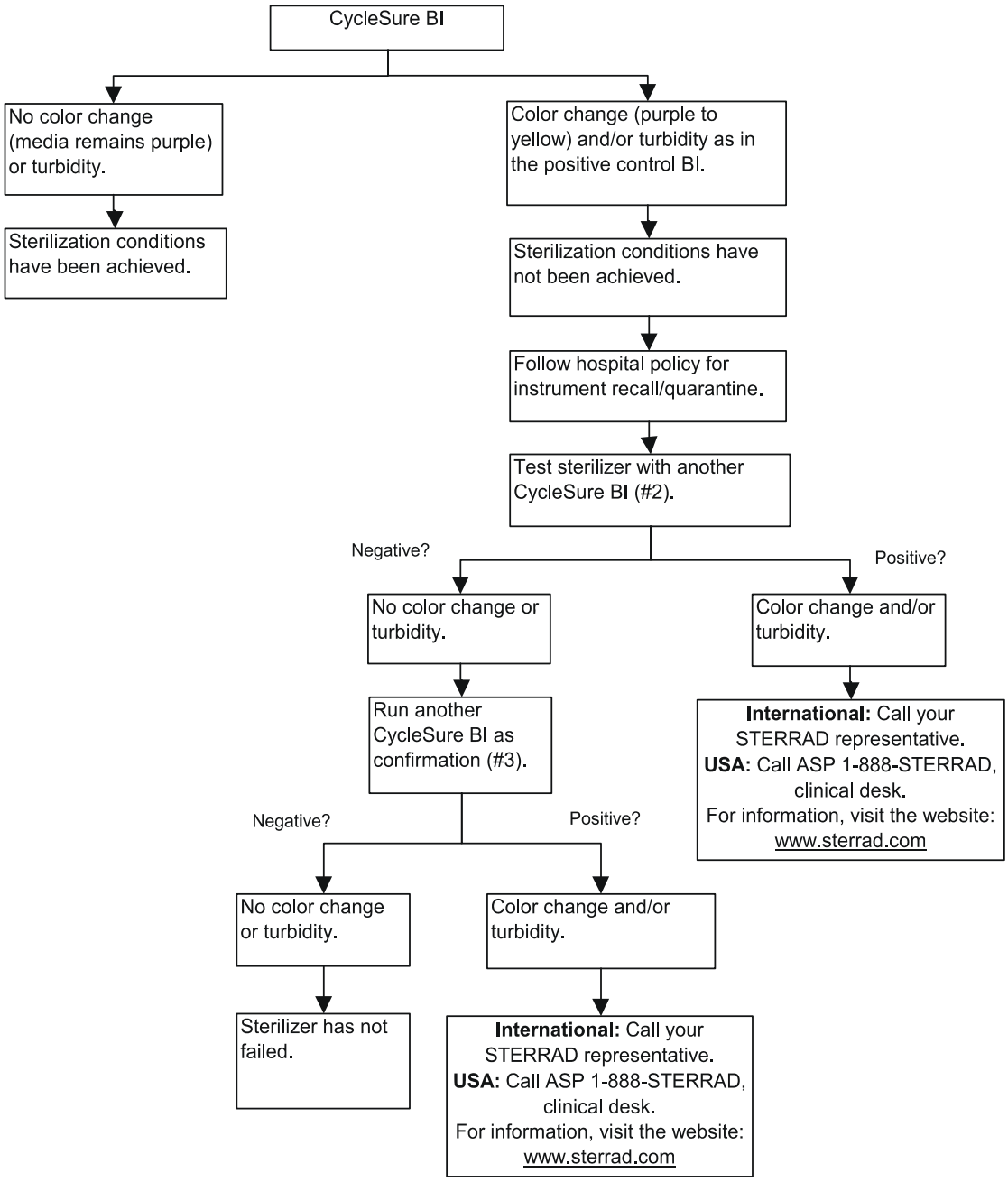
- Contact your ASP Representative regarding biological indicators specifically designed for use in STERRAD Sterilizers.

ASP Biological Indicators contain microorganisms that are known to be resistant to the sterilization process and are one way to verify proper processing. The biological indicator should be placed on the two-tier shelf, at the back part of the bottom shelf. Review the instructions that are included with the biological indicators for proper use. Should a cancellation occur when a biological indicator is in the chamber, discard the biological indicator and use a new biological indicator when starting the next cycle.

Suspected Positive BI

The following flowchart details the steps you need to follow when a positive biological indicator result is received. The flowchart details the procedures for the STERRAD CycleSure® Biological Indicator.

STERRAD® CycleSure® Biological Indicator



Chemical Indicators

STERRAD Chemical Indicator Strips and STERRAD SealSure® Chemical Indicator Tape offer additional ways to verify processing in the sterilization cycle. They should be used in addition to, not in place of, the biological indicator. STERRAD Chemical Indicator Strips and STERRAD SealSure® Chemical Indicator Tape *do not* indicate sterilization; they only indicate that the indicator has been exposed to the hydrogen peroxide. The color of the Chemical Indicator Strips and Tape changes from red to gold (or lighter) when exposed to hydrogen peroxide.

✔ ***Note:*** *Use only ASP biological indicators, STERRAD SealSure® Chemical Indicator Tape, and/or STERRAD Chemical Indicator Strips. Do not use indicators designed for other sterilization processes.*

Using Chemical Indicator Strips

Place STERRAD Chemical Indicator Strips in trays and pouches to show exposure to hydrogen peroxide during the sterilization cycle. Please refer to the *Instructions for Use* included with the STERRAD Chemical Indicator Strips for more information.

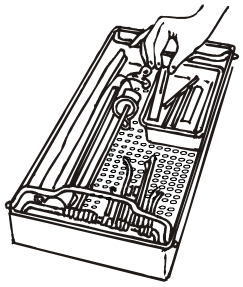


Figure 7. STERRAD® Chemical Indicator Strips should be used in each instrument tray.

Using Chemical Indicator Tape

STERRAD SealSure® Chemical Indicator Tape should be used to secure the polypropylene sterilization wrap around the instrument tray.

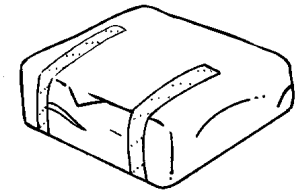


Figure 8. STERRAD® SealSure® Chemical Indicator Tape should be used to secure the polypropylene wrap around each instrument tray.

Please refer to the *Instructions for Use* included with the STERRAD SealSure® Chemical Indicator Tape for more information.

Preparing the Two-Tier Shelf

The procedures listed here must be followed for safe placement of the trays and pouches on the two-tier shelf when used with the carriage.

- Make sure the two-tier shelf is fully seated on the carriage and locked to the carriage before placing items on the two-tier shelf. The alignment wheels on the bottom of the two-tier shelf should be on the outside of the carriage rails.
- Place items on the two-tier shelf so that the items do not protrude from the sides, the back, the top, or the front. The two-tier shelf may be loaded from any position that is comfortable.
- Do not stack trays on top of each other.
- Do not place pouches directly on the shelves.
- When the carriage has been unloaded, it should be located in areas where it will not impede foot traffic. Follow your facility's policy for storage of such items.
- If the two-tier shelf is being used without the carriage, it must remain inside the sterilizer and be firmly locked in place.

Creating the Load Item Data List

The following steps assume that your sterilizer has been configured to use a password and a load list, and that you have logged into the system (see the section on "Starting a Cycle" for complete login information). If it does not require a load list, you may skip this section and go directly to the section on transferring the load into the sterilizer.

1. Enter the ID and password information as shown later in this chapter. The item list entry or load list display is shown. The load list can be entered in three ways:

Figure 9. Type or scan load item data. Touch Keyboard to expand or collapse the keyboard display

WARNING! DO NOT LOOK DIRECTLY AT THE LIGHT IN THE SCANNER HEAD. DO NOT POINT THE SCANNER AT PEOPLE.

- Scan a pre-determined list using barcodes and the barcode scanner. Point the scanner head at the barcode and touch the button. An audible beep is heard when the barcode is successfully read. The red light must cover the barcode from left to right.

- Enter a list using the virtual keyboard and touching the "typewriter" keys on the display. After entering load item information touch **Enter**. A new line appears prompting you to enter the next item. As multiple items are entered, the list expands and up and down scroll arrows appear on the right hand side of the list.

- Use an external keyboard the same way as shown above to enter the information.

  ✔ ***Note:*** *The external keyboard must be attached and the system booted in order to function.*

2. Touch **Done** to complete the entry of the load list.

3. If you would like to enter additional information pertaining to the load such as the doctor's name, etc., follow this step. Otherwise you may go to step 5. Touch **GO TO...** to open the function button bar. Touch **Cycle Notes** to open the Notes display. Enter any text information that is exclusive to this load (use the up and down arrows to scroll through the information). This information can be printed separately by touching **Print**. It also prints as part of the process completion data.

4. Touch **Done** to complete the entry of the notes.

5. Touch **Start Cycle** to begin the cycle as shown in the "Starting a Cycle" section.

Transferring the Load into the Sterilizer

The load is easily transferred on the two-tier shelf into the sterilizer using the following steps:

1. Move the carriage containing the tray-filled two-tier shelf to the sterilizer.

   ✔ ***Note:*** *Metal objects must not come into contact with the chamber walls, the doors or the electrode. Contact with the walls, doors, or electrode could damage the sterilizer or instruments. The door should remain closed when not in use.*

2. Verify that the sterilizer status is ready to use and the door is open.

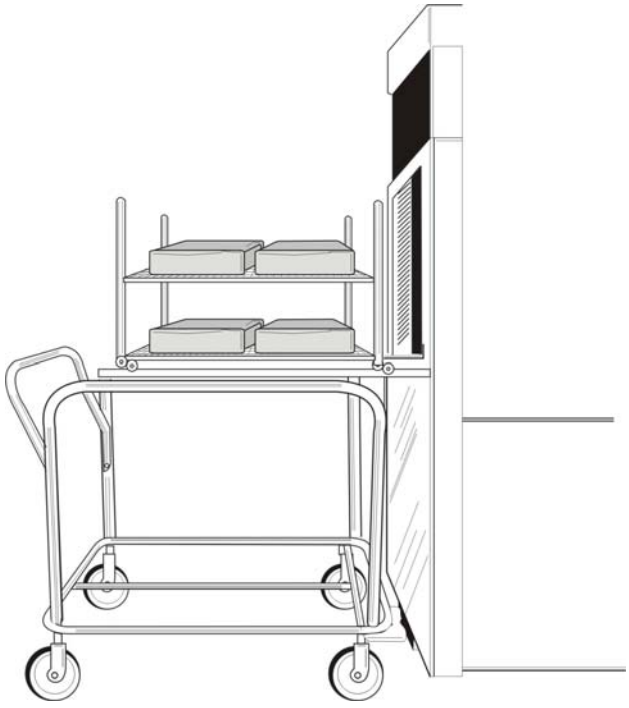


Figure 10. Make sure the carriage is completely seated and locked into the foot mechanism.

3. Gently push the carriage into the sterilizer so that the foot mechanism on the bottom of the sterilizer contacts and locks into the flange at the bottom of the carriage. The top front of the carriage rests just inside the chamber.

4. Release the two-tier shelf using the release. Gently push the two-tier shelf forward into the sterilizer. Make sure the alignment wheels are correctly positioned on the rails for smooth movement. Continue pushing until the two-tier shelf is completely inside the chamber and it engages the inside stop.

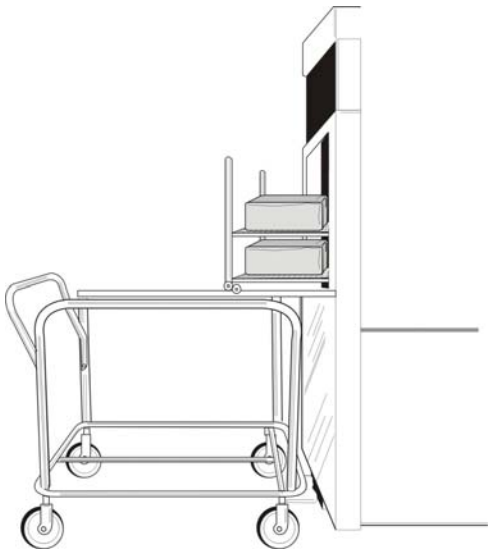


Figure 11. Push the two-tier shelf completely into the chamber.

5. Step on the carriage release and move the carriage to the desired location.

6. Verify that no part of the two-tier shelf or its contents comes in contact with the door or electrode. Close the door and begin your desired cycle or go to the section on “Inserting a Cassette.”

Inserting a Cassette

The STERRAD 200 Sterilizer uses hydrogen peroxide, contained in special cassettes, to sterilize items placed into the sterilization chamber. Each STERRAD 200 Cassette provides enough hydrogen peroxide for 2 cycles. The message screen of the STERRAD 200 Sterilizer notifies you when a new cassette is needed.

WARNING! STERRAD 200 CASSETTES CONTAIN CONCENTRATED HYDROGEN PEROXIDE, A STRONG OXIDIZER. CONCENTRATED HYDROGEN PEROXIDE IS CORROSIVE TO SKIN, EYES, NOSE, THROAT, LUNGS, AND GASTROINTESTINAL TRACT. DIRECT CONTACT WITH THE SKIN CAN CAUSE SEVERE IRRITATION. IF SKIN CONTACT OCCURS, IMMEDIATELY FLUSH WITH LARGE AMOUNTS OF WATER. IF SYMPTOMS ARE SEVERE OR PERSIST, CONSULT A PHYSICIAN IMMEDIATELY.

DIRECT CONTACT WITH EYES CAN CAUSE IRREVERSIBLE TISSUE DAMAGE. IF EYE CONTACT OCCURS, IMMEDIATELY FLUSH WITH LARGE AMOUNTS OF WATER AND IMMEDIATELY CONSULT A PHYSICIAN.

INHALATION OF MIST CAN CAUSE SEVERE IRRITATION OF LUNGS, THROAT, AND NOSE. IF INHALATION OCCURS, MOVE TO FRESH AIR AND CONSULT A PHYSICIAN IMMEDIATELY.

INGESTION CAN PRODUCE CORROSION THAT MAY BE LIFE-THREATENING. IF SWALLOWED, DRINK PLENTY OF WATER IMMEDIATELY TO DILUTE. DO NOT INDUCE VOMITING. CONSULT A PHYSICIAN.

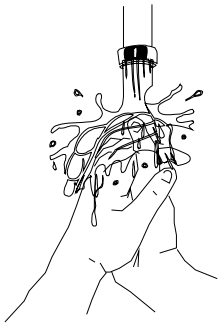


Figure 12. If skin contact occurs, immediately flush the area with water.

WARNING! DO NOT REMOVE THE PLASTIC WRAPPER FROM THE CASSETTE PACKAGE IF THE INDICATOR STRIP IS RED. RED INDICATES DAMAGE. CALL THE ASP CUSTOMER CARE CENTER FOR CREDIT.

To insert a cassette, do the following:

1. Confirm that the sterilizer display indicates that a new cassette is needed.

2. Confirm that the chemical indicator strip on the cassette sleeve is NOT red; red indicates a damaged cassette and concentrated hydrogen peroxide may be present.

3. Confirm that the cassette expiration date has not passed.

   ✔ ***Note:*** *The system considers the cassette expired 8 days after insertion regardless of the printed expiration date. The cassette is ejected at that time. Once the cassette has been removed, even if it was not used, the barcode is rendered unreadable and the cassette cannot be reinserted.*

4. Remove the plastic wrapping from the cassette sleeve. Do NOT remove the cassette from the remaining cardboard sleeve.

5. Orient the arrow so that the top of the cassette sleeve is pointing away from you.

6. Hold the cardboard sleeve by its edges and insert it into the sterilizer.

7. Firmly push the cardboard sleeve in until it can go no further. If positioned properly, the cassette moves into place.

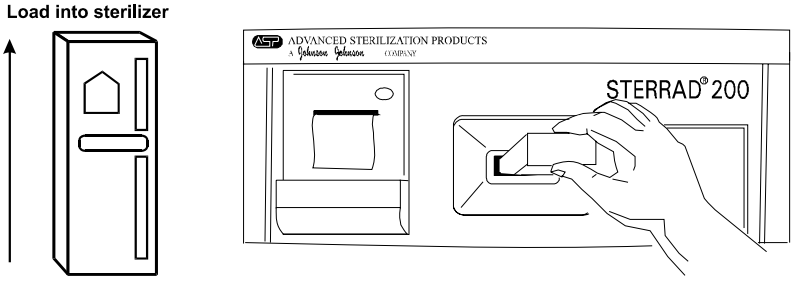


Figure 13. Insert the cassette and sleeve into the sterilizer. This illustration shows the printer on the input side. Your system may be different.

8. If the cardboard sleeve is not pushed in all the way, the monitor continues to read INSERT CASSETTE.

9. If the cardboard sleeve is properly positioned, the cassette is automatically accepted and positioned for use by the sterilizer. The display reads CASSETTE ACCEPTED.

10. If the cassette is not accepted because the barcode cannot be read or the cassette has expired, PLEASE REMOVE CASSETTE is displayed. Should this occur, remove that cassette and insert a valid one.

✔ ***Note:*** *The system microprocessor monitors the status of the cassette and informs the operator when the cassette is empty or expired. Empty or expired cassettes must be replaced prior to starting a cycle.*

WARNING! DO NOT REMOVE USED CASSETTES FROM THE PROTECTIVE CARDBOARD SLEEVE. DISPOSE OF THE CASSETTE INSIDE THE PROTECTIVE SLEEVE FOLLOWING YOUR FACILITY'S PROCEDURES. IF THE USED CASSETTE FALLS OUT OF THE SLEEVE, WEAR CHEMICAL RESISTANT LATEX, PVC (VINYL), OR NITRILE GLOVES TO PLACE THE PLASTIC CASSETTE BACK IN THE ORIGINAL SLEEVE.

Please refer to the *Instructions for Use* included with the STERRAD 200 Cassette for more information.

Starting a Cycle

✔ ***Note:*** *You must read, understand, and follow "Chapter 2. For Your Safety" prior to starting a cycle.*

This display appears following log out, or after power shut down. Touch the screen to view the displays needed to enter a password (if the system is configured for this function), enter a load item list (if the system is configured for this function), and start the sterilization process. The ability to perform certain functions prior to starting a cycle is determined by whether the system requires an ID and password. See the section on "Entering a Password" for more details.

Figure 14. Touch the main display to begin.

Entering a Password

Your system administrator should assign you a log in ID and a password. You must use the ID and password in order to create a load list. You can log in to the system in 3 ways, (touch **Keyboard** to expand or collapse the virtual keyboard):

- Type your ID and password using the virtual keyboard and touching the keys.
- Type your ID and password using an external keyboard (the keyboard must be connected and then the system must be rebooted).
- Scan your ID and password using the external barcode scanner.

If your log in or ID is not recognized, you are prompted to repeat the log in procedure.

Figure 15. Enter ID and password

You would enter the load item list, if that function is available, at this point. Load item list information is shown previously in this chapter.

Password Levels

Following are the various password levels assigned at installation. These levels can only be changed by someone with Administrator access (Level 3) or by an ASP Field Service Engineer (Level 4). Password levels are optional. They can be used (or not) if a password is set at installation.

Password Level	Function Access Capabilities
Level 4-Service	• All the functions of password levels 1-3. • Assign and change passwords of all levels. • Access to service menus.
Level 3-Administrator	• Assign/change passwords for level 1 and level 2 users. • Change the date and time. • Run a cycle. • Enter notes.
Level 2-Programmer	• Run a cycle. • Enter notes.
Level 1-Operator	• Run a cycle. • Enter notes.

When your ID and password are accepted, the following display is shown: Touch **Start Cycle** to begin or touch **Back** then **GO TO . . .** to display the Function Button Bar.

You are ready to start the cycle after the following has taken place: the load has been correctly placed on the two-tier shelf and transferred to the sterilizer; the biological and chemical indicators are in place; and the load list, if any, has been entered.

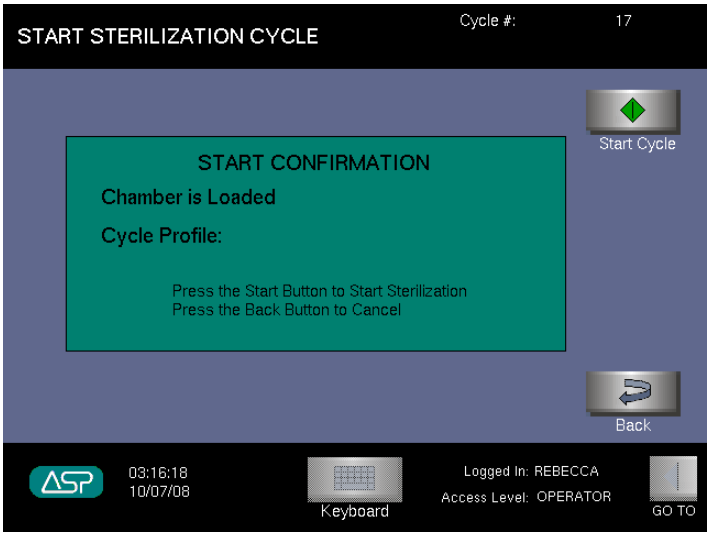


Figure 16. Touch Start Cycle to begin sterilization.

Cycle Notes

The Cycle Notes screen allows you to enter additional information about the current cycle.

To display Cycle Notes, first display the Function Button Bar, then touch **Cycle Notes**.

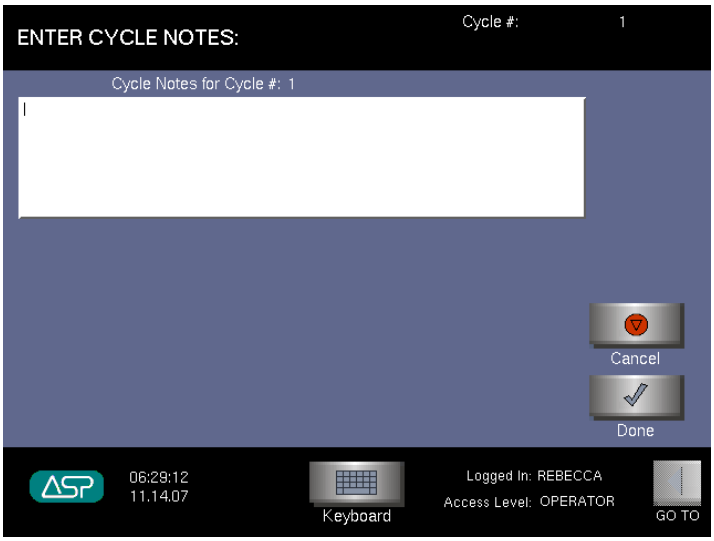


Figure 17. Enter additional cycle information.

Use the virtual keyboard to enter cycle notes information in the indicated field. When you are finished, touch **Done**. The information you entered is added to the cycle history file.

Watching a Cycle

You can monitor the progress of a cycle by watching the display; it indicates the phase of the cycle and certain process parameters. A long beep signals that the cycle is complete.

The display indicates the status of the unit at all times: the current stage of the sterilization cycle; the temperature in the chamber; the pressure in the chamber; the cycle start time, and the cycle estimated end time. You can change the display to show a graph or a numerical readout of the cycle. Each load goes through nine consecutive stages: vacuum, pre-plasma, injection, diffusion, plasma, injection, diffusion, plasma, and vent.

Figure 18. Cycle In Progress–Graph Display. Your display may look slightly different.

Figure 19. Cycle In Progress–Numerical Display.

Completing a Cycle

Cycle completion is signaled as follows:

- A long beep sounds.
- The paper printout (on the input side) shows the process parameters (in black letters only; red letters usually indicate a problem).
- For two door configurations requiring an ID and password: Cycle Completed Successfully is shown on the display. You are automatically logged out from the input side and must log in to the output side to open the door and remove the load. After the load is removed, touch **Done** and **Close Doo**r to log out from the output side.
- For one-door configurations requiring an ID and password: Cycle Completed Successfully is shown on the display. After the load is removed, touch **Done** and **Close Door** to activate the log in screen for the next load.

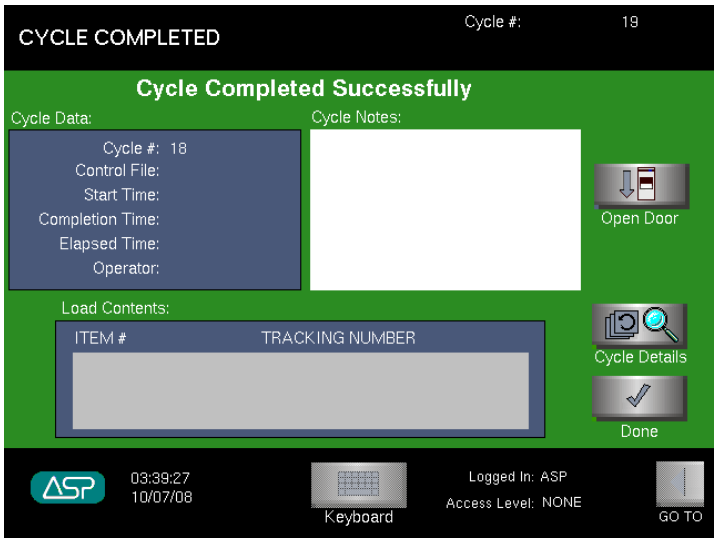


Figure 20. Cycle Complete display for systems requiring an ID and password.

Figure 21. Cycle Complete-Touch Okay, then log in on the output side.

- For two door configurations where no log in has been set up: Cycle Completed Successfully is shown on the display and only the output side is active. You must touch **Open Door** FROM THE OUTPUT SIDE. Remove the load and touch **Done** and **Close Door** to activate the input side display.

- For one-door configurations where no log in has been set up: Cycle Completed Successfully is shown on the display. Touch **Open Door**, remove the load and touch **Done** and **Close Door**.

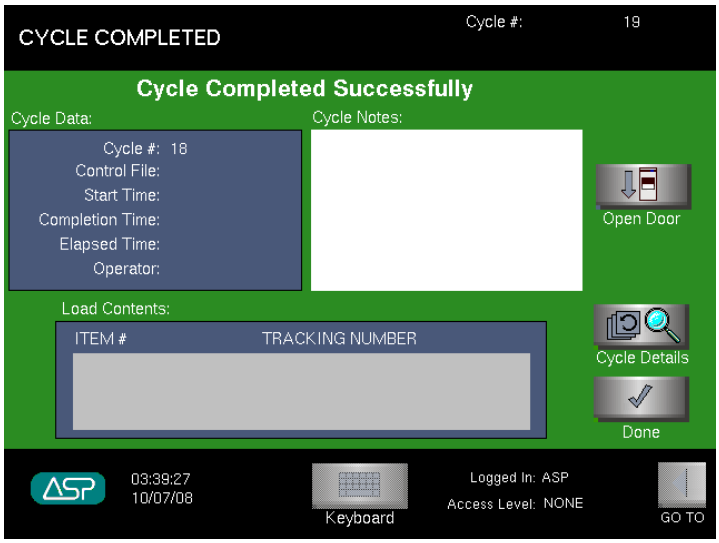


Figure 22. Cycle Completed Successfully.
This display may look different depending on your login.

Logging Out-Two Door Systems

After the sterile items have been removed from the output side, and no further review of the information is necessary, you should log out from the system. This returns control to the input side. To log out from the output side, do the following:

1. Touch **GO TO...** to open the toolbar. Touch **Login**.
2. Logout Confirmation is displayed.
3. Touch **YES** (or Confirm) to log out.
4. Touch **Cancel** to cancel the log out procedure and view the previous display.

Canceled Cycles

You can cancel a cycle at any time by touching **Cancel Cycle**, except during the final vent phase. The STERRAD 200 Sterilizer may also cancel a cycle if it detects a problem with the cycle. The load from a canceled cycle can only be removed from the input side.

To manually cancel a cycle:

1. Touch **Cancel Cycle**.

2. Cancel Confirmation is displayed.

3. Touch **YES** to confirm cancellation and cancel the cycle. Touch **NO** to return to the Cycle in Progress display.

4. Ten beeps sound and the Cycle Canceled/Operator Cancellation message is displayed.

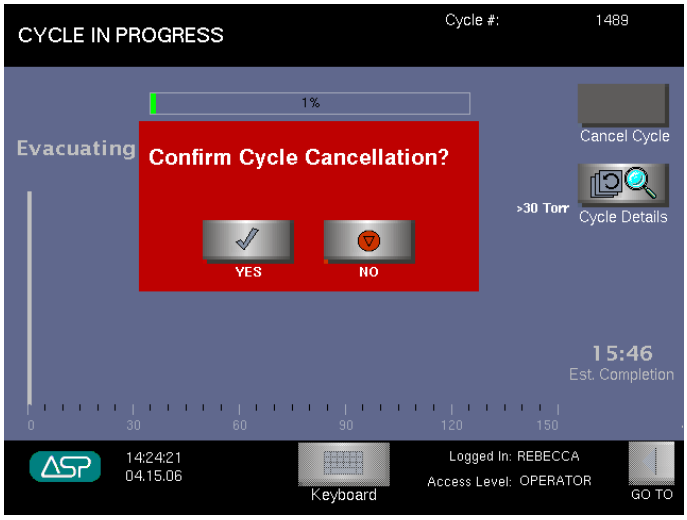


Figure 23. Touch Cancel to start a manual cancellation. The display requests confirmation of the cancellation. Touch YES to confirm. Touch NO to return to the previous display.

5. A paper printout exits the printer with a message in red ink.

6. The sterilizer automatically completes the cancellation process (which includes a short plasma stage during most phases of the process).

✔ ***Note:*** *The exact sequence of cancellation actions depends on which process was in operation at the time of cancellation.*

7. The display indicates when cancellation is complete and a summary display appears.

Loads from canceled cycles should be re-wrapped using new polypropylene wrap, STERRAD Chemical Indicator Strips, and STERRAD SealSure® Chemical Indicator Tape. If a biological indicator was used in the canceled load, a new one should be placed in the chamber before restarting the new cycle.

WARNING! IF A CYCLE CANCELS AND THE ITEMS IN THE LOAD APPEAR WET, HYDROGEN PEROXIDE MAY BE PRESENT. WEAR CHEMICAL RESISTANT LATEX, PVC (VINYL), OR NITRILE GLOVES WHILE REMOVING THE ITEMS FROM THE CHAMBER, AND TO WIPE OFF THE ITEMS WITH A DAMP CLOTH. DISPOSE OF THE CONTAMINATED CLOTH ACCORDING TO YOUR FACILITIES PROCEDURES.

Automatic Cancellation

If the sterilizer control system cancels a cycle, the display indicates when the cancellation process is complete. As with manual cancellation (above), the load should be repackaged using new polypropylene wraps, chemical indicators, etc. Note the messages on the display and on the paper printout, and refer to “Chapter 6. Troubleshooting” for more information.

Additional System Information

Under certain conditions the system may not perform normally and yet not generate a message. This is particularly true during power failures or low power situations. If there is a power failure, a leak in the pneumatic system can cause the door (doors) to open without power being present. It is possible that hydrogen peroxide would be present at that time. Take precautions when unloading a system in these situations. If it is anticipated that the power will be off for more than 24 hours, call your ASP service representative for additional instructions.

WARNING! CONCENTRATED HYDROGEN PEROXIDE IS CORROSIVE TO SKIN, EYES, NOSE, THROAT, LUNGS, AND GASTROINTESTINAL TRACT. IF A CYCLE CANCELS AND THE ITEMS IN THE LOAD HAVE ANY VISIBLE MOISTURE OR LIQUID, HYDROGEN PEROXIDE MAY BE PRESENT. YOU MUST FOLLOW ALL SAFETY PRECAUTIONS REQUIRED FOR DEALING WITH HYDROGEN PEROXIDE.

Unloading and Handling

After ensuring that the STERRAD Chemical Indicators exhibit the correct color change, the sterilized items are ready for immediate use, following your facility's policies and procedures. No additional time for aeration is required because the by products are water vapor and oxygen. Follow your facility's policy for release of sterilized items.

On a two-door system, the input side displays are locked at the completion of a cycle. You must access the display from the output side in order to remove the load.

1. Log in to the system using your assigned ID and password as shown previously.

2. Touch Open Door.

3. Move the empty carriage to the sterilizer if you are using it to transfer the load.

4. Push the carriage gently into the sterilizer so that the foot mechanism on the bottom of the sterilizer contacts and locks into the flange at the bottom of the carriage. The top front of the carriage rests just inside the chamber and releases the latch holding the two-tier shelf in the sterilizer.

5. Gently pull the two-tier shelf onto the carriage. Make sure the alignment wheels are correctly positioned on the rails for smooth movement.

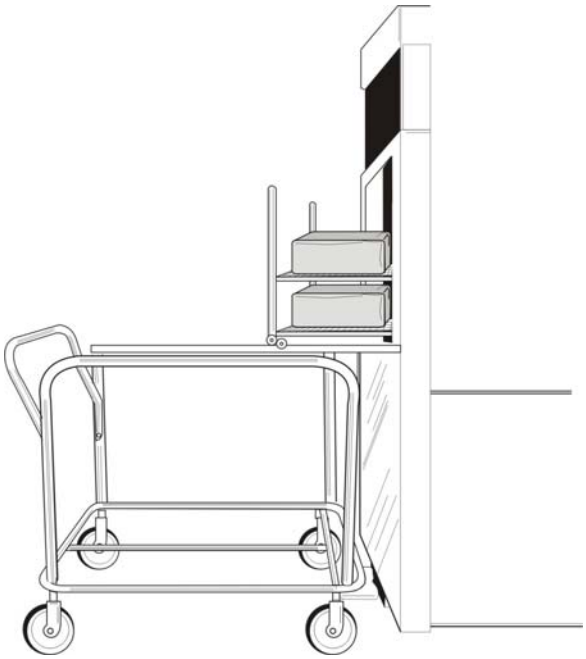


Figure 24. Make sure the carriage is correctly positioned and locked to the foot mechanism. Pull the two-tier shelf gently onto the carriage.

6. Continue pulling until the two-tier shelf is completely seated on the carriage and is locked in place.

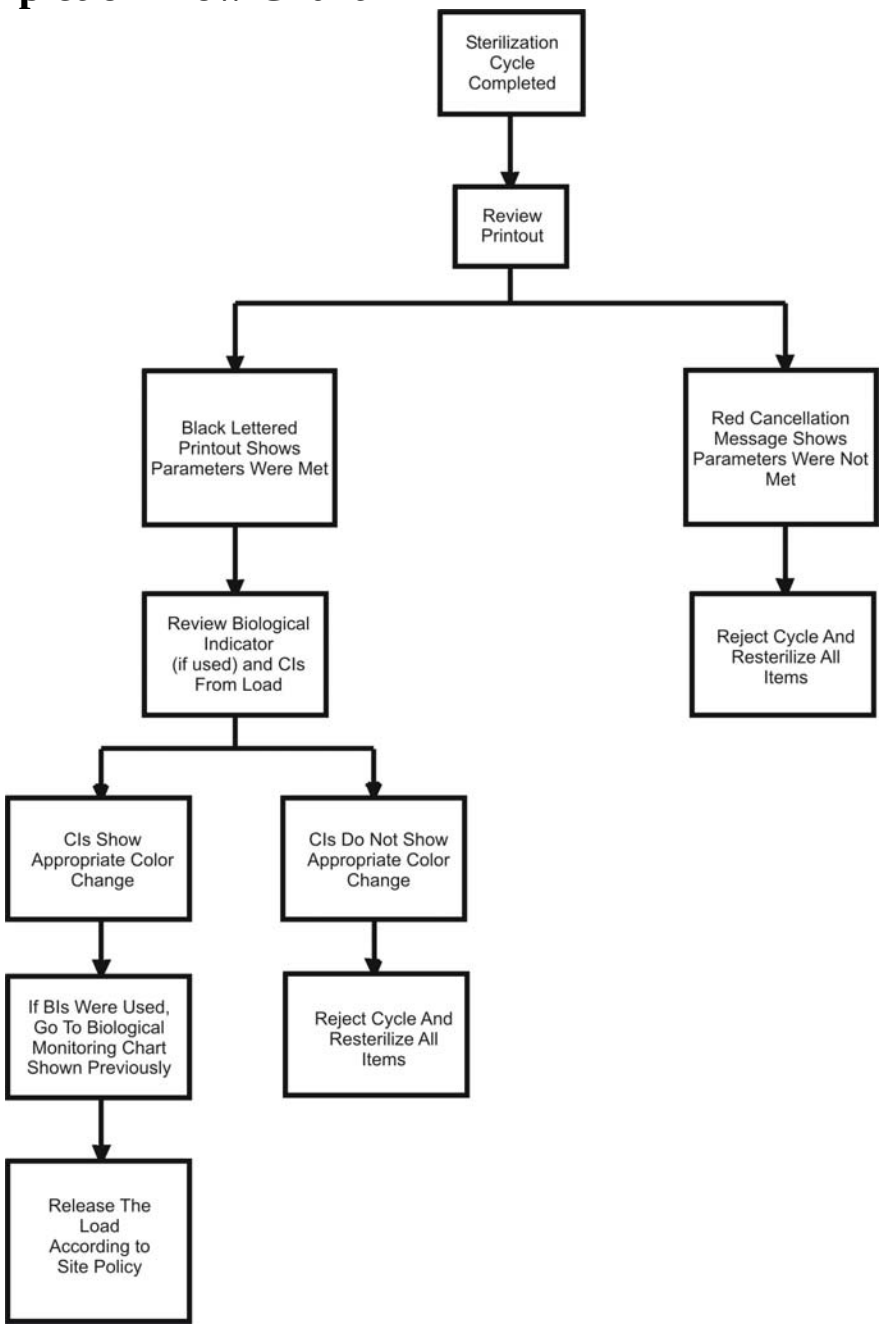
7. Step on the carriage release and move the two-tier shelf and carriage to the desired location.

8. Touch Close Door.

Transferring the Load Without Using the Carriage

1. Touch **Open Door**.
2. Move a trolley or supply cart to the sterilizer.
3. Transfer the sterilized items to the trolley/cart.
4. Move the transferred items to the desired location.
5. Touch **Close Door.**

Cycle Completion Flow Chart



Cassette Control

From time-to-time it may be necessary to control the function of the cassette or to view the cassette barcode data. You may do that by using the H_2O_2 Control. This button is located on the Function Button Bar and is accessible to all password levels. To use the "Cassette Control" function, do the following:

1. Touch **GO TO . . .** to display the Function Button Bar.

2. Touch **H_2O_2 Control.** The following is displayed.

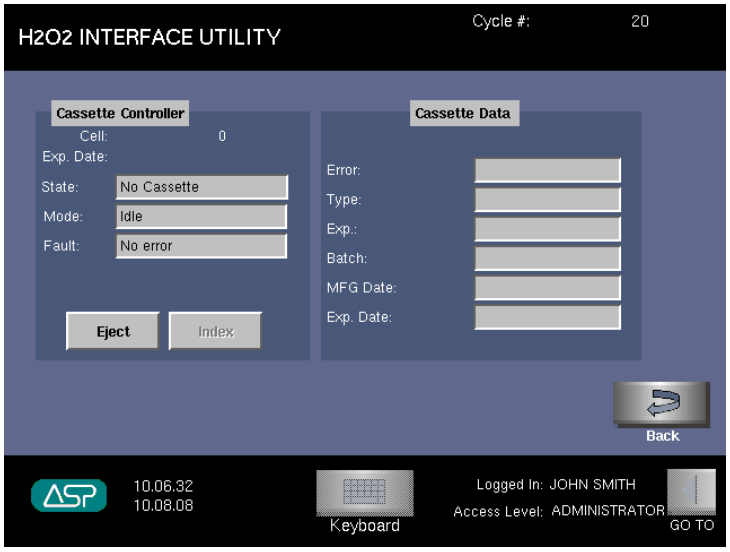


Figure 25. H_2O_2 Interface Utility or Cassette Control.
Touch H_2O_2 Control on the Function Button Bar to view this display.

- Touch **Eject** to eject a cassette that is stuck in the chute.
- The Index function is only available to Service level passwords.
- State and Mode refer to the status of the sterilizer.
- Fault displays the sterilizer error message, if any.
- Cassette Data displays the information contained in the barcode, which is automatically scanned when the cassette is inserted into the sterilizer. If the cassette is not usable, the error information is displayed in the error field.

Obtaining a Cycle History

Administrator access is needed to perform this function. To review the cycle history, do the following:

1. Touch **GO TO…** to open the toolbar.

2. Touch **Utilities**, then touch **Cycle History.**

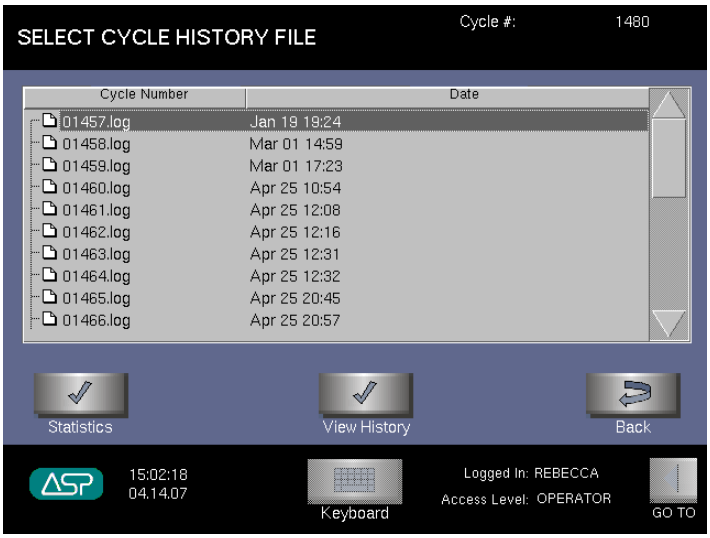


Figure 26. Cycle History Display. Depending on system configuration, the file size column may not be displayed.

3. The Cycle History display contains information about the previous 1500 cycles. The display shows the name of the cycle (assigned by the system), the size of the data file (not available on all configurations), and the cycle date and time. Touch the file name and then touch **View History**, which shows details of the highlighted file including load item data. Touch **Statistics** to view cycle cancellation information. In addition, the View History display has a cycle history button that provides more detail on the particular cycle including a cycle graph and the ability to print the cycle information.

4. When you are done viewing a display, touch **Back** to return to the previous display.

Figure 27. Touch View History to see this display.

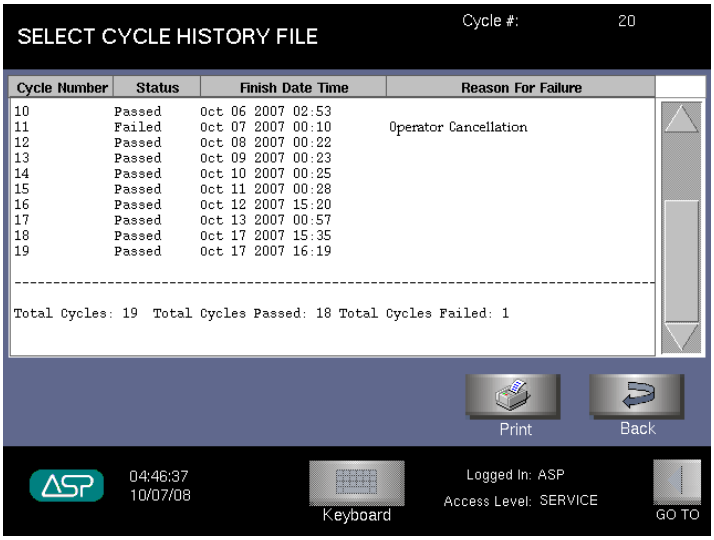


Figure 28. Touch Statistics to see this display.

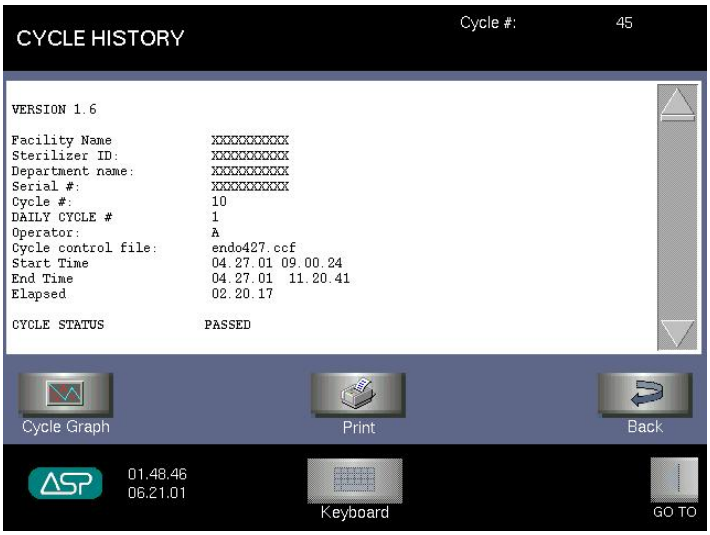


Figure 29. From the View History Display, Touch Cycle History to see this display. Touch Print to print the displayed information.

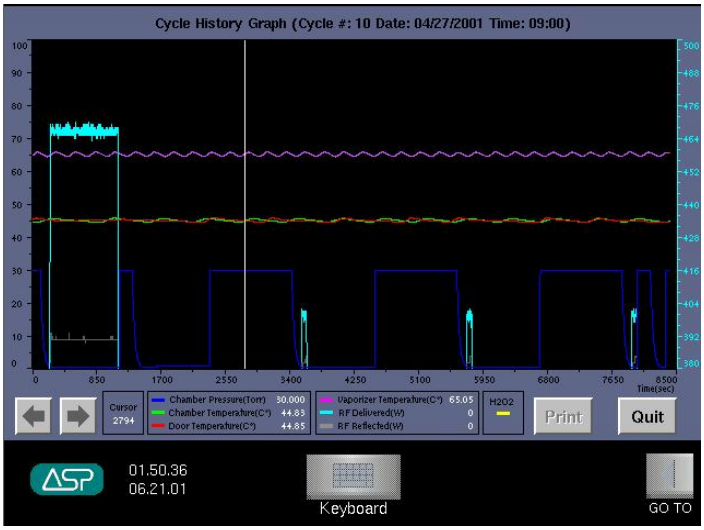


Figure 30. Touch Cycle Graph from the previous display to see this display. The arrows advance through the graph. Touch Print to print the displayed information. Touch Quit to return to the previous display.

Administrative Functions

The password level “Administrator” allows you to perform functions that are not available at the “Operator” level. These functions include: assigning and modifying passwords, changing the date and time displayed on the sterilizer, configuring the sterilizer to function on a network, and assigning the system ID information. These displays and descriptions of their functions are shown in this section.

System Setup

Touch **System Setup** on the Utilities Menu to display the Configuration Menu. The Configuration Menu allows you to select any of four configuration options.

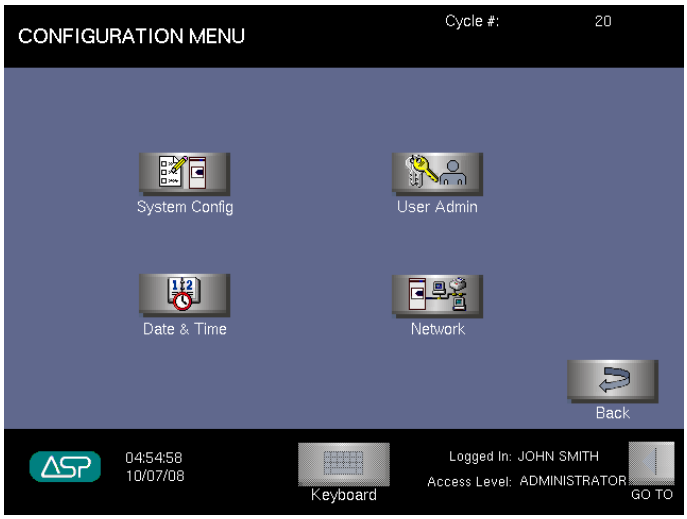


Figure 31. Touch System Setup to view this menu.

- Touch **System Config** to display basic configuration parameters for the STERRAD 200 Sterilizer.
- Touch **User Admin** to display user names, passwords, and privileges.
- Touch **Date & Time** to enter the display that allows you to change the date and time for the system clock and calendar.
- Touch **Network** to display and/or update the optional network connection parameters.

System Configuration Screen

To display the System Configuration screen, touch **System Config** on the Configuration Menu.

The System Configuration screen allows you to display and/or enter identifying and configuration information about the sterilizer. This information is typically entered at the factory or by an ASP service technician when the sterilizer is installed and is ordinarily not changed in the field.

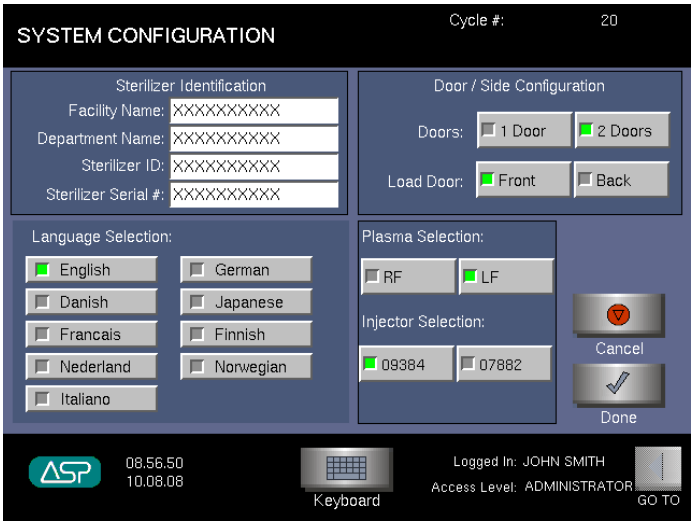


Figure 32. System Configuration.

- The Sterilizer Identification block allows you to enter the name of your facility and a label that identifies the individual machine. The serial number is displayed for information purposes and cannot be changed by the user.
- The Door/Side Configuration block indicates the number of doors and which door is used for cycle loading.
- The Language Selection block allows you to choose the language used on all sterilizer displays.
- Touch **Done** to return to the Configuration Menu.
- Touch **Cancel** to cancel any changes you made to fields in the System Configuration screen.

User/Password Administration Screen

To display the User/Password Admin screen, touch **User Admin** on the Configuration Menu.

The User/Password Administration screen allows you to add new users, modify users, and assign passwords and access privileges.

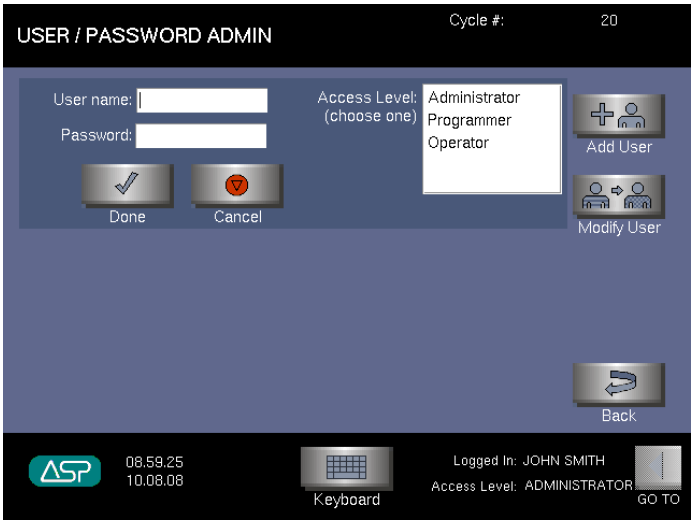


Figure 33. User/Password Administration.

Adding a New User

1. Touch **Add User** to add a new user to the system.
2. In the Username field, type the new user's name.
3. In the Password field, type the new user's password.
4. In the Access Level list box, choose the appropriate access level for the new user. You cannot assign a "Service" access level – this is reserved for ASP Service personnel only.
5. To cancel an addition, touch **Cancel**. To accept the new entry, touch **Done**. To return to the Configuration Menu, touch **Back**.

Modifying an Existing User's Information

1. Touch **Modify User** to change the password or access privileges of an existing user.

2. In the Username field, enter the name of the user to be modified.

3. In the Password field, enter the user's password.

4. In the Access Level list box, choose the appropriate access level for the user. You cannot assign a "Service" access level – this is reserved for ASP Service personnel only.

5. To cancel a change, touch **Cancel**. To accept the modified information, touch **Done**. To return to the Configuration Menu, touch **Back**.

Resetting the Date and Time

The date and time are set by your Service Representative at installation. If you have an administrator level password, you can change these settings at any time to conform to local standards.

✔ ***Note:*** *Date and Time are also available on the Function Button Bar on systems configured to operate without an ID or password login.*

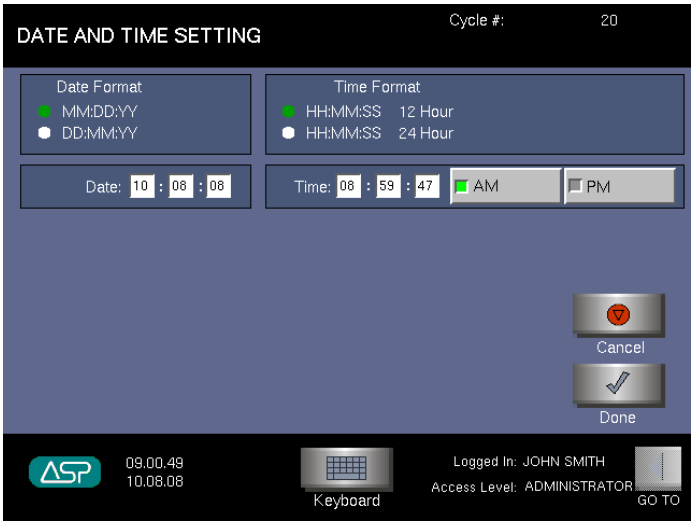


Figure 34. Date And Time Display.

To change the date

1. Touch **GO TO…**, then touch **Utilities**.
2. Touch **System Setup**, then touch **Date and Time**.
3. Touch the **Date Format** you desire. The radio button (green dot) should light by your selection.
4. Touch the **Date** field. Touch **Keyboard** and using the number keys, enter the correct date.
5. Touch **Done** to accept and save the entered information. Touch **GO TO…** to exit the display.
6. Touch **Cancel** (the red circle) at any time to cancel and exit without saving.

To change the time

1. Touch the **Time** format you desire. The radio button should be green by your selection.
2. Touch the **Time** field. Touch **Keyboard** and using the number keys, enter the correct time.
3. Touch **AM** or **PM** if applicable for your desired time format.
4. Touch **Done** (the check mark) to accept and save the entered information. Touch **GO TO...** to exit the display.
5. Touch **Cancel** (the red circle) at any time to cancel and exit without saving.

Network Settings Screen

✔ ***Note:*** *This function should not be performed arbitrarily. Please call your ASP service representative for help configuring these settings.*

The Network Settings screen allows the users with administrator level passwords access to configure the host name and port number when the sterilizer is connected to a network.

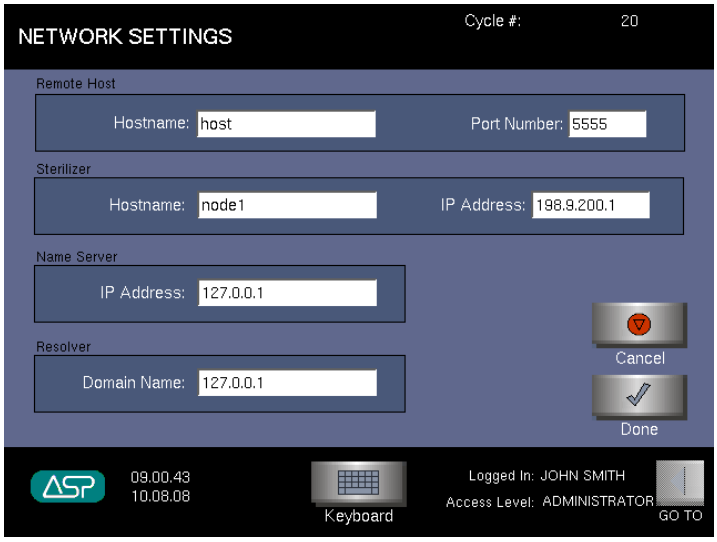


Figure 35. Network Settings.

1. Use the virtual keyboard to enter the host name in the “Hostname” field and the network port number in the “Port Number” field.

2. When you have entered the information, touch **Done** to update the network configuration.

3. To leave this screen without making any changes to the displayed data, touch **Cancel**.

Chapter 5.

Routine Maintenance

Overview

This chapter is provides details regarding the following maintenance procedures for the STERRAD® 200 Sterilizer:

- Replacing the printer cartridge
- Replacing the printer paper
- Cleaning the STERRAD 200 Sterilizer

Contact the ASP Customer Care Center for guidance on performing any other maintenance procedures.

WARNING! ONLY EXPERIENCED TECHNICIANS WHO ARE FULLY TRAINED TO MAINTAIN THE STERRAD 200 STERILIZER SHOULD REPAIR OR ADJUST THIS UNIT. USE OF UNAUTHORIZED PARTS FOR MAINTENANCE OR REPAIR COULD CAUSE PERSONAL INJURY, RESULT IN COSTLY DAMAGE OR UNIT MALFUNCTION, AND WILL VOID THE WARRANTY.

CAUTION: Regularly scheduled, or Planned Maintenance (PM) must be performed at the interval specified on the system. Make sure you schedule a service call in a timely manner when notified that a PM is due.

Maintaining the Printer

The printer requires that the ribbon cartridge be replaced whenever the print becomes too light to read easily. The paper should be changed when the colored bars begin to appear on the paper. This indicates the paper supply is running low.

Replacing the Printer Ribbon Cartridge

To replace a printer cartridge do the following:

1. Open the printer access service door on the upper left.
2. Remove the used cartridge by firmly, but carefully, pulling on the right side, as indicated by the arrow on the cartridge.
3. Discard the used cartridge.
4. Insert a new cartridge by aligning the left side of the cartridge in the printer. Push on the right side of the cartridge to snap it into place.

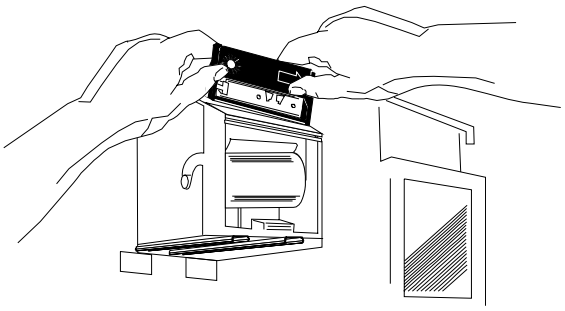


Figure 36. Tilt the ribbon cartridge into position and snap it in place.

5. Turn the knob on the cartridge clockwise to remove any slack from the ribbon.
6. Feed the printer paper through the printer paper slot in the service door and close the printer access service door.

Replacing the Printer Paper

To replace the paper roll do the following:

1. Open the printer access service door on the upper left.

2. Remove the empty paper core and discard the core. Retain the metal paper roller and insert it into the new roll of paper.

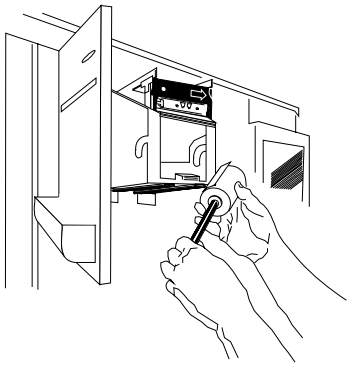


Figure 37. Retain the metal roller and insert it into the new paper core.

3. Place a new paper roll into position so that the paper feeds from the back of the roll. You may need to tilt the paper so that the roller fits securely into the grooves.

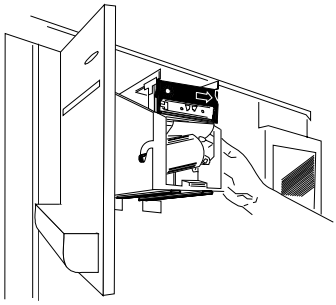


Figure 38. Tilt the paper roll into one side of the printer, then set it into the other side. The paper feeds from the back.

4. Feed the edge of the paper into the slot behind the printer. Press the **Paper Advance** button on the door until the mechanism begins to pull the paper. Continue pressing **Paper Advance** until about 150 to 160 mm (6 inches) of paper exits the printer cartridge.

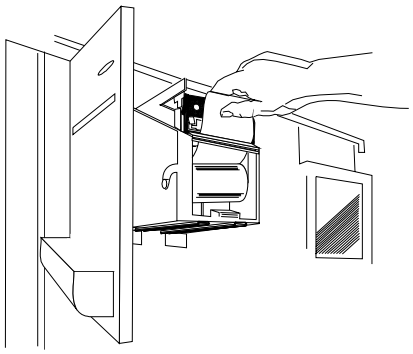


Figure 39. Feed the paper up through the mechanism and then through the slot in the door.

5. Feed the printer paper through the slot in the access door and close the door.

Cleaning the Sterilizer

The outside surfaces of the sterilizer can be cleaned with water and a mild detergent. The inside of the sterilization chamber does not normally require cleaning. The chamber door and the chamber should not be cleaned with an abrasive, such as a wire brush or steel wool. If you have any questions regarding cleaning the STERRAD 200 Sterilizer, call your ASP service representative.

CAUTION: Do not clean the chamber door area with abrasives. The sterilization chamber uses an O-ring vacuum seal to maintain a vacuum in the chamber. Never use rough cleaning tools, such as a wire brush or steel wool on the door housing or chamber assembly. This could damage the seal. Use a damp, lint free cloth to clean the chamber door.

Chapter 6.

Troubleshooting

Overview

The STERRAD® 200 Sterilizer is a relatively trouble-free device, requiring only routine maintenance and care in load preparation to help prevent system cancellations.

WARNING! YOU MUST WEAR CHEMICAL RESISTANT LATEX, PVC (VINYL), OR NITRILE GLOVES WHEN REMOVING A LOAD AFTER A CYCLE CANCELLATION.

Rebooting the System

Rebooting is used in certain troubleshooting procedures. When power is turned off then back on, it causes the computer in the sterilizer to reload the software control program automatically; this action "reboots" the sterilizer. (Rebooting is used in certain troubleshooting procedures.) The display indicates sterilizer status after power has been reapplied.

The Power ON-OFF switch is located on the service side of the sterilizer (this is to the right as you face the input side of the sterilizer). If instructions indicate that you should reboot the system, flip the switch to the OFF position. Wait a few seconds for the system to completely power down, then flip the switch to the ON position. The display indicates sterilizer status after power has been reapplied.

Using the Message Table

To use this table, look at the message displayed and then find the same message in the table (it is in alphabetical order). The table shows the message, the printout associated with the displayed message, and suggests some actions to take. If you touch **Help** when any message is displayed, you receive additional solutions and actions to take. You may receive similar messages during different stages of the system cycle. The action you are to take is usually the same regardless of the cycle stage.

If your question was not answered either by the table below or by using the "Help" display, call the ASP Customer Care Center for more information.

Message Table

Displayed Messages	Printed Messages	Condition/Action
Delivery Subsystem Failure	Delivery Subsystem Failure	The system was unable to successfully complete the injection. Call the ASP Customer Care Center.
H_2O_2 Delivery Failure	H_2O_2 Delivery Failure (System parameters are included on printout.)	Acceptable hydrogen peroxide concentration was not detected. Insert a new cassette and run the cycle again. If the problem persists, call the ASP Customer Care Center.
Insert New Cassette	No Printout	Insert a new cassette and restart the sterilizer.
Operator Cancellation	Operator Cancellation	The operator has cancelled the cycle. Restart the sterilizer.
Power Failure	Power Failure	The power was turned off during a cycle. Restart the sterilizer
RF Subsystem Failure	RF Subsystem Failure (RF system parameters are included on printout.)	**WARNING!** If plasma failed to light, please use extra caution when handling load. Make sure the shelf or other metal objects are not in contact with the electrode, door, or chamber walls. Repackage and reprocess load. If problem persists, call the ASP Customer Care Center.
Temperature Has Not Risen	No Printout	The sterilizer is not at the temperature

Displayed Messages	Printed Messages	Condition/Action
Call ASP Technical Service		needed to run a cycle. Call the ASP Customer Care Center.
Temperature Out Of Range	Temperature Out Of Range (System temperature parameters are included on printout.)	The door, chamber, vaporizer, or tube temperatures are above or below the operating temperatures. Call the ASP Customer Care Center.
Timeout Failure	Timeout Failure	A timeout event occurred when the sterilizer was unable to complete a task within a preset timeout period. Run the cycle again, if the timeout problem persists, call the ASP Customer Care Center.
Vacuum System Failure	Vacuum System Failure (Vacuum system parameters are included on printout.)	The load may contain too much moisture contain cellulose material or there may be too many packages in the chamber. If problem persists, start a cycle with an empty chamber. If the vacuum stage is still not successful, call the ASP Customer Care Center.
Warming Up **Please Wait**	No Printout	You must wait until the system warms up to run a cycle.

Appendix A.

Specifications

Space Requirements	
Sterilizer Size	Width: 915 mm (36 inches) Depth: 1130 mm (44 ½ inches) Height: 1754 mm (69 inches)
Weight	475 kg/1047 lbs.
Operation	
Electrical Operation	208 VAC, 60 Hz 3 phase WYE, 20 amps NEMA L21-20 receptacle, CBA phase rotation
Ambient Temperature	+18° C to +40° C (+64° F to +103° F)
Relative Humidity	10% to 85% up to +30° C ambient and linearly decreasing from 85% at +30° C to +70% at +40° C noncondensing
Air Exchanges	Minimum 10/hour
Heat Generation	1919 BTU/Cycle
Pollution Degree	2
Installation Category	II
Atmospheric Pressure	700 hPa to 1060 hPa
Altitude	Up to 2000 meters

Installation (please call ASP at 1-888-STERRAD before re-installing the sterilizer)	
Space Requirements	225.4 cm H x 291.5 cm W x 213.0 cm D (88.7 in x 114.8 in x 83.7 in)
Mobility	Freestanding unit: Movable In-Wall Unit: Mounted movable freestanding unit or mounted in-wall unit
Venting Requirements	None required
Gas Tank Requirements	None required
Electrical Requirements	3 m/10 ft. power cord
Weight	475 kg/1047 lbs.
Equipment Rating	
High Voltage	200V~, 3~, 50/60 Hz, 4 wire, 15 A 208V~, 3~, 50/60 Hz, 5 wire, 15 A 380V~/400V~/415V~, 3~, 50/60 Hz, 5 wire, 15 A
Electrical Requirements	
The STERRAD® 200 Sterilizer should only be plugged into outlets approved by a qualified technician. For further requirements, refer to the label on the back panel of the sterilizer or call your ASP service representative. Only a qualified technician can determine when the STERRAD 200 Sterilizer can be safely moved to a new power source.	
Protection	
Protection Class	Class 1
Protection Against Ingress of Water	Ordinary (IPXO)
Mode of Operation	Continuous
I/O Connections	
Keyboard	DIN-5 Type
Barcode	D-SUB 9 Type

Transport and Storages	
Ambient Temperature	-40° C to +70° C (-40° F to +158° F)
Relative Humidity	10% to 85% up to 30° C ambient and linearly decreasing from 85% at 30°C to 70% at 40°C
Atmospheric Pressure	500 hPa to 1060 hPa

✔ ***Note**: ASP provides circuit diagrams, component part lists, descriptions, and calibration instructions on request to appropriately qualified personnel on the assemblies that ASP feels are serviceable by non-ASP personnel.*

Explanation of Warning Symbols	
IEC 378-0300 	Attention, consult accompanying documents
IEC 878-03-0 	Dangerous voltage
	**Caution**: Mechanical crushing hazard. Do not touch
	**Caution**: Mechanical crushing hazard when door is closing.
	Protective earth
3N	Three phase neutral
I/O	On/Off
	Alternating current
	The door must be blocked before maintenance is performed.